

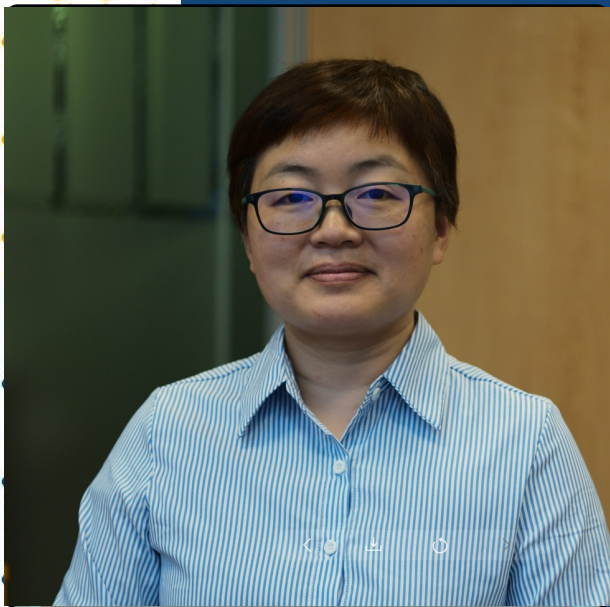


2023
EUROPE
INTERCHANGE
COPENHAGEN | 26-27 APRIL



Questionnaires, Ratings, and Scales Data Standards and Handling

Presented by Jintao Shi, Data Manager, BDS, Boehringer Ingelheim



Meet the Speaker

Jintao Shi

Title: Data Manager

Organization: Boehringer Ingelheim

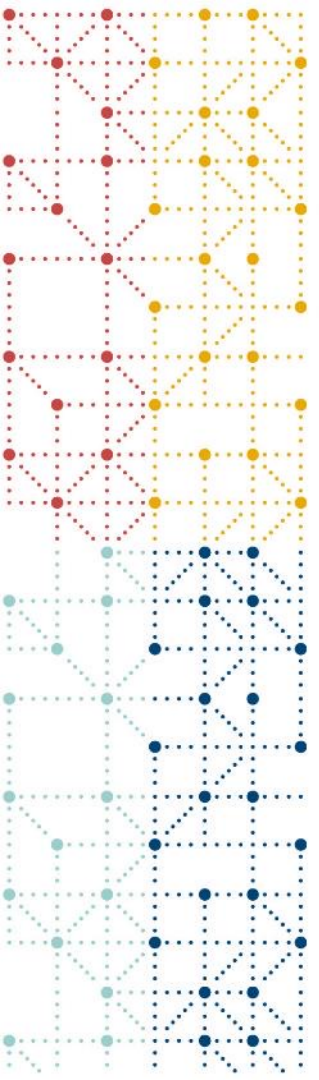
Major in molecular biology during the master study.

With work experience as CRA, Data Manager and SGA



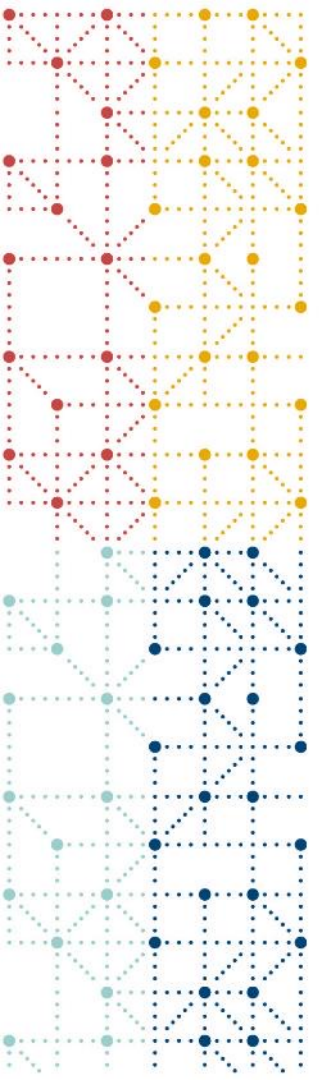
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. CDISC QRS Standards
2. QRS Handling Practice
3. Sponsor QRS Library



CDISC Standards for QRS

CDISC Standards for QRS

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[Questionnaires, Ratings and Scales \(QRS\)](#) - Each QRS instrument is a series of questions, tasks or assessments used in clinical research to provide a qualitative or quantitative assessment of a clinical concept or task-based observation.

The QRS team develops [Controlled Terminology](#) and [SDTM](#) (tabulation) supplements; the ADQRS Team develops [ADaM](#) (analysis) supplements.

[SDTMIG](#)

[RDF](#)

[CORE](#)

[ADaM](#)

[SDM-XML](#)

[CDISC Biomedical Concepts](#)

[QRS](#)

Terminology

[Digital Data Flow](#)

[Medical Devices](#)

[Glossary](#)

[Genomics](#)

[Controlled Terminology](#)



QRS Standards - Description

Description

QRS Supplements

New QRS Supplements

FAQ

QRS Resources

Clinical Outcome Assessment (COA)

Named, well defined instrument

Reliable and sensitive to change

Content validity and construct validity

Fit for purpose, context of intended use

CDISC creates supplements for four types of instruments:

- **Questionnaires:** 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

- **Functional Tests:** 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

- **Clinical Classifications and Disease Response:** Clinical Classifications and Disease Response instruments or criteria are represented in the Disease Response and Clin Classification (RS) domain.

- **Clinical Classifications:** Named instruments whose output is an ordinal or categorical or biological status. Usually, the instrument will be published in a professional journal or professional's observation of a subject's health condition or status with input from data from clinical records or may involve a clinical judgment or interpretation of physical or subject status. These physical manifestations may be findings that are typical Clinical Classifications may be composite scores based on diverse inputs. This as seen in questionnaires.

- **Disease Response:** Named instruments or criteria whose output provides information may include eradication of detectable disease, stabilization of disease, or disease progression. This information will be obtained from trained healthcare professionals and may include data (e.g., CT Scan, MRI). Data from these criteria or instruments may be represented as a response instrument, the extent of disease response (e.g., partial response) would be represented in PR.

ECOG PERFORMANCE STATUS

Grade ECOG

- | | | |
|--------------------------|---|---|
| <input type="checkbox"/> | 0 | Fully active, able to carry on all pre-disease performance without restriction |
| <input type="checkbox"/> | 1 | 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 |
| <input type="checkbox"/> | 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours |
| <input type="checkbox"/> | 3 | Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours |
| <input type="checkbox"/> | 4 | Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair |
| <input type="checkbox"/> | 5 | Dead |

RSSTRES/RSSTRESN

RSORRES when RSTESTCD = ECOG101

QRS Standards –QRS Supplements

Description **QRS Supplements** New QRS Supplements FAQ QRS Resources

How can I access the published supplements?

QRS Supplements

Displaying 1 - 280 of 280

SDTM Domain/ADaM Dataset Permission

QRS Name Starts With

QRS Name Contains

SDTM Domain/ADaM [

Permission

--CAT Contains

Apply

QRS Name	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version Release Date
10-Meter Walk/Run	10-METER WALK/RUN	ADaM	Public Domain	Version: 1.0 17 Feb 2022
10-Meter Walk/Run	10-METER WALK/RUN	FT	Public Domain	Version: 1.0 18 Jan 2022
12-Item Multiple Sclerosis Walking Scale	MSWS-12	QS	No Response Received	N/A
6 Minute Walk Test	SIX MINUTE WALK	FT	Public Domain	Version: 1.0 21 May 2014
Abnormal Involuntary Movement Scale	AIMS	PS	Public Domain	Version: 1.0

About 200 QRS supplements are published:

- QRS Types
 - >10 Functional Tests,
 - About 50 Clinical Classifications
 - >100 Questionnaires
- Disease areas most frequently covered
 - Mental health
 - Neurology
 - Endocrine

QRS Standards - FAQ

Description

QRS Supplements

New QRS Supplements

FAQ

QRS Resources

What is included in a QRS Supplement?

Are there QRS-like instruments for which

How does the FDA Clinical Outcome Assessment (COA) program relate to QRS supplements?

I don't see any domains other than QS in

What are the different types of FDA COAs?

What are the different ADaM data structures

How is QRS low and high anchor information for visual analog scales (VAS) and numeric rating scales (NRS) handled?

Where can I find QRS Controlled Terminology

How does CDISC develop QRS Supplements?

How does CDISC handle copyrighted instruments

How can I get involved in developing CDISC QRS supplements?

What do I do if the instrument I'm interested in

How can I access the published supplements?

What QRS supplemental variable names are included in QRS supplements?

QRS Standards – QRS Resources

Mainly for QS-FT-CC

- General Business Rules
- --CAT Rules
- --TEST-CD Rules
- Response Rules

Description QRS Supplements New QRS Supplements FAQ **QRS Resources**

QRS Naming and Business Rules

QRS Supplement Request Form

QRS Therapeutic Area User Guide COA Cross Reference Table

FACIT Item Bank

QRS NSV Registry FT QS RS Summary

Through the ePROVIDE platform and the PROQOLID, PROLABELS and PROINSIGHT databases, Mapi Research Trust creates vital links among those at every level of Patient-Centered Outcomes studies.

Visit <https://eprovide.mapi-trust.org/> for more information.

CDISC and Mapi Research Trust work together to ensure copyrighted instruments are available to CDISC to create QRS supplements by leveraging PROQOLID™, Mapi Research Trust's comprehensive online database designed to assist academic researchers, physicians, students, pharmaceutical companies, health authorities, and international organizations in the search and evaluation of COAs.

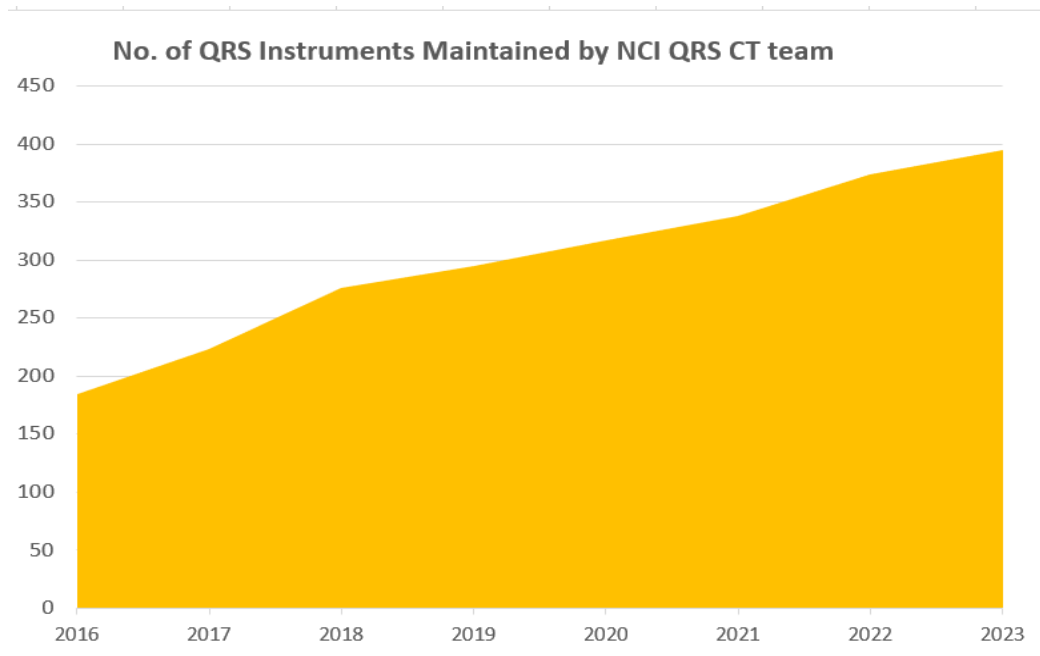
Dozens of approved QRS specific NSV
For example:

- *Anchor Text High and Low*
- *Anchor Numeric Value High and Low*
- *Conditional Branched Item Indicator*
- *Collected Administrator Identifier*
- *Preprinted Administrator Identifier*
- *Preprinted Respondent Identifier*

- About 200 QRS instruments referred in 35 TAUGs

QRS Controlled Terminologies

- About **50%** SDTM and ADaM controlled terminologies (CT) terms are for QRS
- Continue to increase



QRS CT – QS FT CC Category

For about 400 QRS instruments

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C118971		Yes	Category of Clinical Classification	CCCAT	Category of Clinical Classification	A grouping of observations within the Disease Response and Clin Classification domain.	CDISC Clinical Classification Category Terminology
C102111	C118971		Category of Clinical Classification	AIMS	AIMS01	Abnormal Involuntary Movement Scale (AIMS) (Guy W. Ed. ECDEU Assessment Manual for Psychopharmacology. Rockville MD: US Dept of Health, Education and Welfare. 1976. Publication No. (ADM) 76-338). CDISC believes this instrument to be in the public domain, but you should perform your own assessment.	Abnormal Involuntary Movement Scale Clinical Classification
C115304		Yes	Category of Functional Test	FTCAT	Category of Functional Test	A grouping of observations within the Functional Tests domain.	CDISC Functional Test Category Terminology
C141686	C115304		Category of Functional Test	10-METER WALK/RUN	Ten Meter Walk/Run; TENMW1	10-Meter Walk/Run (McDonald CM, Henricson EK, Abresch RT, et al. The 6-minute walk test and other clinical endpoints in duchenne muscular dystrophy: reliability, concurrent validity, and minimal clinically important differences from a multicenter study. Muscle Nerve. 2013;48(3):357-68.). CDISC believes this instrument to be in the public domain, but you should perform your own assessment.	10-Meter Walk/Run Test Functional Test
C100129		Yes	Category of Questionnaire	QSCAT	Category of Questionnaire	A grouping of observations within the Questionnaires domain.	CDISC Questionnaire Category Terminology
C187516	C100129		Category of Questionnaire	ABC	ABC01	Activities-Specific Balance Confidence Scale (ABC) (Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol A Biol Sci Med Sci. 1995 Jan;50A(1):M28-34. ABC scale Anita M. Myers, 1995. All rights reserved.). No part of the Activities-Specific Balance Confidence Scale may be reproduced, distributed, or transmitted in any form or by any means, including photocopying, recording, or other electronic or mechanical methods, without the prior written permission of Anita M. Myers and payment of any applicable fees. Copyright Anita M. Myers, 1995. All rights reserved.	Activities-Specific Balance Confidence Scale Questionnaire

QRS CT – QS FT CC Test Code and Test Name

QRS –TEST-CD (for about 320 QRS instruments) **about 19900 rows**

QRS response --ORRES/STRESC (for about 15 QRS instruments) **>700 rows**

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C182464		No	Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	AIMS0101T07OR	Abnormal Involuntary Movement Scale Clinical Classification
C182674	C182464		Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	Mild	AIMS0101 through AIMS0107-Mild
C182673	C182464		Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	Minimal, may be extreme normal	AIMS0101 through AIMS0107-Minimal, may be extreme
C182675	C182464		Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	Moderate	AIMS0101 through AIMS0107-Moderate
C182672	C182464		Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	None	AIMS0101 through AIMS0107-None
C182676	C182464		Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	Severe	AIMS0101 through AIMS0107-Severe
C182502		No	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	AIMS0101T07STR	Abnormal Involuntary Movement Scale Clinical Classification
C182677	C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	0	AIMS0101 through AIMS0107-0
C182678	C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	1	AIMS0101 through AIMS0107-1
C182679	C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	2	AIMS0101 through AIMS0107-2
C182680	C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	3	AIMS0101 through AIMS0107-3
C182681	C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	4	AIMS0101 through AIMS0107-4
C101805		No	Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS01TC	Abnormal Involuntary Movement Scale Clinical Classification
C102034	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0101	AIMS01-Muscles of Facial Expression
C102035	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0102	AIMS01-Lips and Perioral Area
C102036	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0103	AIMS01-Jaw
C102037	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0104	AIMS01-Tongue
C102038	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0105	AIMS01-Upper Extremities
C102039	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0106	AIMS01-Lower Extremities
C102040	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0107	AIMS01-Neck, Shoulders, Hips
C102041	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0108	AIMS01-Severity of Abnormal Movements
C102042	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0109	AIMS01-Incapacitation due Abn Movements
C102043	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0110	AIMS01-Patient Awareness Abn Movements
C102044	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0111	AIMS01-Current Problems Teeth/Dentures
C102045	C101805		Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS0112	AIMS01-Patient Usually Wear Dentures
C101806		No	Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01TN	Abnormal Involuntary Movement Scale Clinical Classification
C102044	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Current Problems Teeth/Dentures	AIMS01-Current Problems Teeth/Dentures
C102042	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Incapacitation due Abn Movements	AIMS01-Incapacitation due Abn Movements
C102036	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Jaw	AIMS01-Jaw
C102035	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Lips and Perioral Area	AIMS01-Lips and Perioral Area
C102039	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Lower Extremities	AIMS01-Lower Extremities
C102034	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Muscles of Facial Expression	AIMS01-Muscles of Facial Expression
C102040	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Neck, Shoulders, Hips	AIMS01-Neck, Shoulders, Hips
C102043	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Patient Awareness Abn Movements	AIMS01-Patient Awareness Abn Movements
C102045	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Patient Usually Wear Dentures	AIMS01-Patient Usually Wear Dentures
C102041	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Severity of Abnormal Movements	AIMS01-Severity of Abnormal Movements
C102037	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Tongue	AIMS01-Tongue
C102038	C101806		Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01-Upper Extremities	AIMS01-Upper Extremities

QRS CT - ADaM

GAD02 SDTM Test Code and Test Name

Codelist Name	CDISC Submission Value	CDISC Synonym(s)
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Code	GAD02TC	Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Code	GAD0201	GAD02-Feeling Nervous Anxious or On Edge
...
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Code	GAD0208	GAD02-Total Score
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Name	GAD02TN	Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Name	GAD02-Feeling Nervous Anxious or On Edge	GAD02-Feeling Nervous Anxious or On Edge
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Test Name	GAD02-Total Score	GAD02-Total Score
...

GAD02 ADaM Parameter Code and Parameter Name

Codelist Name	CDISC Submission Value	CDISC Synonym(s)
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Code	GAD02PC	Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Code
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Code	GAD02TS	GAD02-Total Score - Analysis
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Name	GAD02PN	Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Name
Generalized Anxiety Disorder - 7 Version 2 Questionnaire Parameter Name	GAD02-Total Score - Analysis	GAD02-Total Score - Analysis

Source SDTM score values may not be suitable for analysis because the values may need to be imputed or transformed. Recalculations of collected values may be needed per analysis rules

CDISC Published QRS Standards

CDISC Published QS-FT-CC Standards	Notes
SDTM CT --CAT	The most basic standard. Synonym and definition are equally important.
SDTM CT –TEST-CD	Test Code and Test Name based on --CAT. May not be available even --CAT is created.
SDTM CT Response Codelist(s)	ORRES and STRESC for some public domain instruments,
QRS Supplement SDTM	Created and maintained by SDS QRS sub-team, normally created after SDTM QRS CT publish.
ADaM CT PARAM-CD	Parameter and parameter code for subscale and total scores of some instrument, and where items from different SDTM versions are combined for analysis purposes.
QRS Supplement ADaM	Maintained by ADQRS team for some QRS instruments.

CDISC wiki – SDS QRS Supplements

QRS Supplement Best Practices

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QRS Supplement Best Practices

Created by STEVE HOPKINS, last modified on 11/11/2022

QRS FAQ Categorized

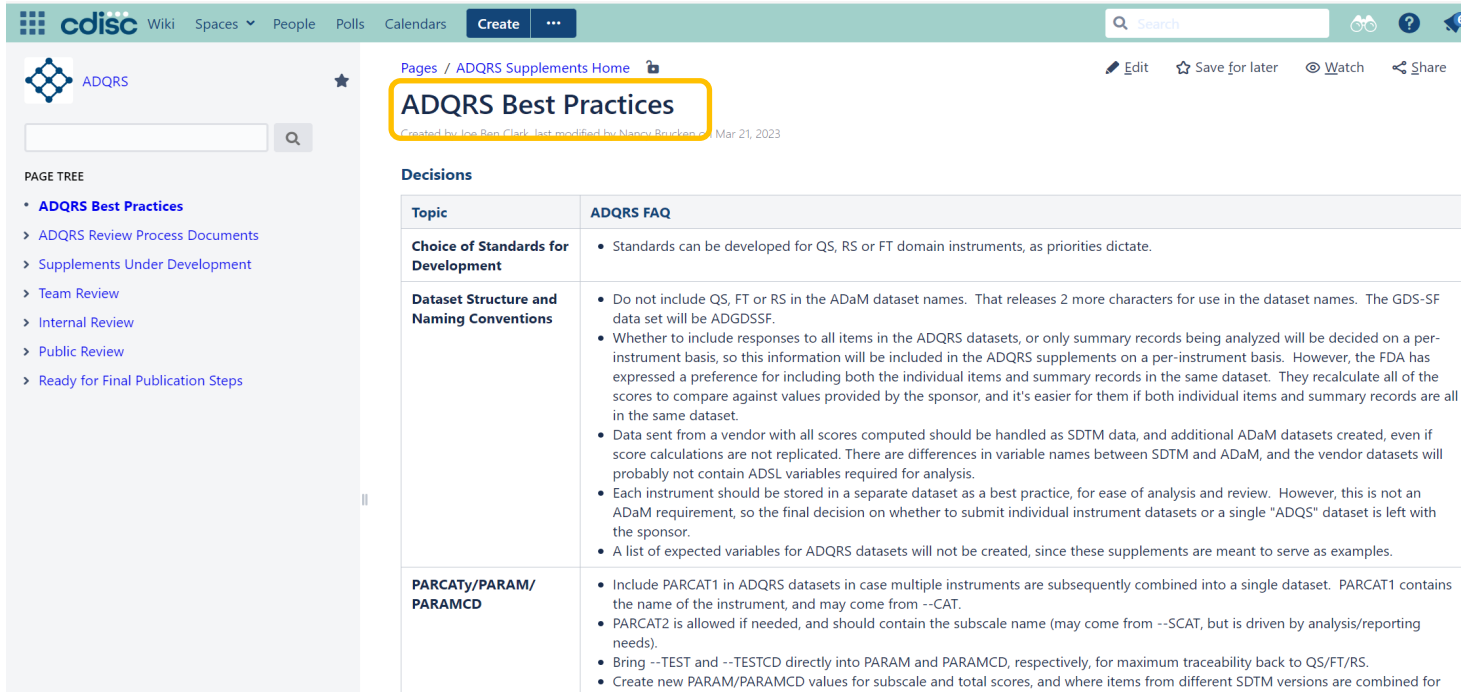
Annotated CRFs	
Topic	QRS FAQ
Annotation Placement	27-Oct-2021: If the scores and reference text are present in each response, annotate the scores in the first question only with QSSTRESC/QSSTRESN. Draw a red or blue box around the scores and place the annotation next to it. Use of the same colored arrows are also useful. Here is an example annotated CRF: PASI V2 CRF.pdf
Format	23-Jun-2021: CRF annotations need to follow the Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG) V2.0 example going forward. https://www.cdisc.org/standards/foundational/sdtmig Legacy Instrument CRF Annotations will be maintained; unless a change control is needed in the future and then the effort to revise will be made. <ul style="list-style-type: none">• 2021-06-23 QRS ** Agenda and Meeting Notes ** documents the QRS subteam moving forward with the SDTM-MSG V2.0 CRF annotations.• In the above-referenced PASI V2, note the following conventions:<ul style="list-style-type: none">◦ dashed lines around the category variable and value in the top right corner to represent data that is not directly collected on the CRF. That is, "RSCAT = PASI V2" has a dashed box around it because that will be the value of RSCAT in the dataset, but that is not collected on the CRF. This convention is also used for the value of the test code for each item (e.g., "RSTESTCD = PASI0201" has a dashed box around it.)◦ --ORRES is the collected original result so it has a solid line around it. Draft guidance for CDISC created QRS instrument CRFs: (this will be updated as more CRFs are created) <ul style="list-style-type: none">• CDISC-created CRFs will have 3 columns, labeled "Item Number", "Item Description", and "Item Response", no quotes, all bolded.• Times New Roman 12 point font should be used for the item text as appropriate.• Times New Roman 18 point font size should be used for the instrument name.• The instrument's reference article should always be included at the end of the CRF.• If the instrument uses multiple pages, the headers should be repeated on each page.• ... (to be continued as additional use cases are identified)
--EVAL/--EVALID	27-Oct-2021: Team decided that --EVAL/--EVALID variables should not be annotated on the CRF.
Response sets	26-Jun-2013: Team made these rules for annotating the CRF and these should be added to the FAO document:



QRS supplement
BP

CDISC wiki – ADQRS Supplements

ADQRS Best Practices



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ADQRS Best Practices

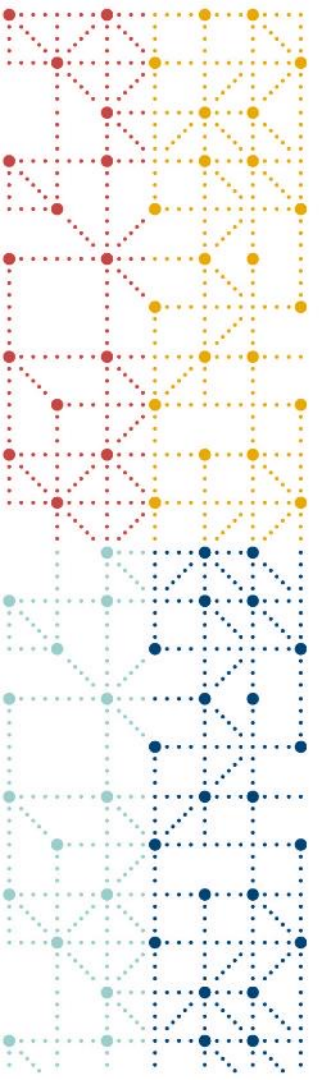
Created by Joe Ben Clark, last modified by Nancy Bruckner on Mar 21, 2023

Decisions

Topic	ADQRS FAQ
Choice of Standards for Development	<ul style="list-style-type: none">Standards can be developed for QS, RS or FT domain instruments, as priorities dictate.
Dataset Structure and Naming Conventions	<ul style="list-style-type: none">Do not include QS, FT or RS in the ADaM dataset names. That releases 2 more characters for use in the dataset names. The GDS-SF data set will be ADGDSSF.Whether to include responses to all items in the ADQRS datasets, or only summary records being analyzed will be decided on a per-instrument basis, so this information will be included in the ADQRS supplements on a per-instrument basis. However, the FDA has expressed a preference for including both the individual items and summary records in the same dataset. They recalculate all of the scores to compare against values provided by the sponsor, and it's easier for them if both individual items and summary records are all in the same dataset.Data sent from a vendor with all scores computed should be handled as SDTM data, and additional ADaM datasets created, even if score calculations are not replicated. There are differences in variable names between SDTM and ADaM, and the vendor datasets will probably not contain ADSL variables required for analysis.Each instrument should be stored in a separate dataset as a best practice, for ease of analysis and review. However, this is not an ADaM requirement, so the final decision on whether to submit individual instrument datasets or a single "ADQS" dataset is left with the sponsor.A list of expected variables for ADQRS datasets will not be created, since these supplements are meant to serve as examples.
PARCATy/PARAM/ PARAMCD	<ul style="list-style-type: none">Include PARCAT1 in ADQRS datasets in case multiple instruments are subsequently combined into a single dataset. PARCAT1 contains the name of the instrument, and may come from --CAT.PARCAT2 is allowed if needed, and should contain the subscale name (may come from --SCAT, but is driven by analysis/reporting needs).Bring --TEST and --TESTCD directly into PARAM and PARAMCD, respectively, for maximum traceability back to QS/FT/RS.Create new PARAM/PARAMCD values for subscale and total scores, and where items from different SDTM versions are combined for



ADQRS BP



QRS Handling Practices

QRS-like But Not QRS

Sponsor-defined general single-Item assessment concepts for assessment of symptoms or other, may be evaluated using sponsor-defined general codelist scales, visual analog scales (VAS) or numeric rating scales (NRS), with extreme variability in data collection and analysis methods.

- ◆ *TAUG [Therapeutic Area User Guide for Psoriasis](#) section 4.2*

Evaluation data based on microscopic data represented in MI domain.

- ◆ *Gleason Score with details in TAUG [Therapeutic Area User Guide for Prostate Cancer](#)*
- ◆ *Global Histologic Disease Activity Score (GHAS) with details in TAUG ([Crohn's Disease Therapeutic Area User Guide](#))*
- ◆ *Robarts Histopathology Index (RHI) with details in TAUG ([Crohn's Disease Therapeutic Area User Guide](#))*

QS, FT and RS Differentiation

- Start with the descriptions on CDISC website for questionnaire, functional test, clinical classification and disease response. CDISC QRS supplements can also be good references.
- **QS vs.RS:** instruments were considered as QS due to historical reason and have been/will be switched to RS

Abnormal Involuntary Movement Scale (AIMS)	Functional Assessment Questionnaire (FAQ)
Barnes Akathisia Rating Scale (BARS)	Functional Assessment Questionnaire (FAQ-NACC)
Baseline Dyspnea Index (BDI)	Karnofsky Performance Scale (KPS SCALE)
Brief Psychiatric Rating Scale-Anchored (BPRS-A)	Kurtzke Expanded Disability Status Scale (EDSS) - to be updated
Disability Rating Scale (DRS)	Kurtzke Functional Systems Scores (KFSS)
Disease Steps	Transition Dyspnea Index (TDI)
Eastern Cooperative Oncology Group Performance Status (ECOG)	Unified Parkinson's Disease Rating Scale UPDRS

- **QS vs.FT:** instruments was considered as QS due to historical reason and will be switched to FT

Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog) – to be updated

Language & UK vs. US version

A	D	UK
		I feel tense or "wound up"
3		Most of the time
2		A lot of the time
1		From time to time, occasionally
0		Not at all
		I still enjoy the things I used to enjoy
0		Definitely as much
1		Not quite so much
2		Only a little
3		Hardly at all
		I get a sort of frightened feeling as if something awful is about to happen
3		Very definitely and quite badly
2		Yes, but not too badly
1		A little, but it doesn't worry me
0		Not at all
		I can laugh and see the funny side of things
0		As much as I always could
1		Not quite so much now
2		Definitely not so much now
3		Not at all
		Worrying thoughts go through my mind
3		A great deal of the time
2		A lot of the time
1		Not too often
0		Very little
		I feel cheerful
3		Never
2		Not often
1		Sometimes
0		Most of the time
		I can sit at ease and feel relaxed
0		Definitely
1		Usually
2		Not often
3		Not at all

A	D	US
		I feel tense or "wound up"
3		Most of the time
2		A lot of the time
1		From time to time, occasionally
0		Never
		I enjoy the things I used to enjoy
0		Definitely
1		Not quite so much
2		Only a little
3		Hardly at all
		I get a sort of frightened feeling as if something awful is about to happen
3		Very definitely and fairly badly
2		Yes, but not too badly
1		Sometimes, but it doesn't worry me
0		Never
		I can laugh and see the funny side of things
0		As much as I always could
1		Not quite so much now
2		Definitely not so much now
3		Never
		Worrying thoughts go through my mind
3		A great deal of the time
2		A lot of the time
1		Not too often
0		Almost never
		I feel cheerful
3		Never
2		Not often
1		Sometimes
0		Most of the time
		I can sit at ease and feel relaxed
0		Always
1		Usually
2		Not often
3		Never

US English is the strongly preferred language for QRS terminology. UK English version will NOT be treated as a separate version if both UK and US versions exist.

HADS (*Hospital Anxiety and Depression Scale*)

UK and US versions for HADS: questions are the same, minor differences on the responses. Use the published CDISC CT for CAT, -- TEST/CD. CDISC does NOT control responses from copyrighted instruments so sponsors may create custom response terminology for UK vs US versions of HADS, which would then be able to describe and distinguish the different responses between the two country versions.

Missing QRS Data

- When any individual QRS instrument item is not done, record for the item shall be populated in SDTM dataset with --STAT="NOT DONE".
- When the whole QRS instrument assessment is not done, "QSALL", "FTALL", and "RSALL" shall **NOT** be used as the Test Code. Authorities recommended to address the missing QRS data **ALWAYS** at the individual item level.
- –REASND shall be populated if the reason for NOT DONE is available, otherwise –REASND shall be set as null.

Conditional Branching Concept

CDISC QRS team discussed with FDA and will be reviewed again 2Q23: if the item is not done due to conditional branching, SUPP datasets prepared to show Conditional Branching Item Indicator as “Y”.

- *When assigned conditionally branched responses are not documented in the instrument’s instructions or a user manual:*

1. QNAM = “--CBRFL”, QLABEL = “Conditional Branched Item Indicator “, QVAL = “Y”
2. --ORRES, --STRESC, and --STRESN are set to null

- *When assigned conditionally branched responses are documented in instructions or a user manual:*

1. QNAM = “--CBRFL”, QLABEL = “Conditional Branched Item Indicator “, QVAL = “Y”
2. The --ORRES responses are represented as “None” for severity items, “Not at all” for interference items
3. If numeric response values are assigned, they are represented as --STRESC /--STRESN. If no numeric response assigned, --STRESC /--STRESN are set to null

--ORRESU/--STRESU Handling

Units are pre-defined in the questions, --ORRESU/--STRESU values are populated

Physiologic Variable	RSTESTCD	High Abnormal Range					Low Abnormal Range				Points
		+4	+3	+2	+1	0	+1	+2	+3	+4	
Temperature - rectal	APCH101	39°-40.9°	30-159	110-129	38.5°-38.9°	36°-38.4°	34°-35.9°	32°-33.9°	30°-31.9°	≤ 29.9°	
Mean Arterial Pressure - mm Hg	APCH102					70-109		50-69		≤ 49	
Heart Rate (ventricular response)	APCH103	≥ 180	140-179	110-139		70-109		55-69	40-54	≤ 39	
Respiratory Rate (non-ventilated or ventilated)	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	APCH105A		350-499	200-349		< 200					
b. FIO ₂ < 0.5 record only PaO ₂	APCH105B					PO ₂ > 70	PO ₂ 61-70		PO ₂ 55-60	PO ₂ < 55	
Arterial pH (preferred)	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)	APCH106B	11-51.9			32-40.9	22-31.9		18-21.9	15-17.9	< 15	
Serum Sodium (mMol/L)	APCH107	160-179	155-159	150-154	130-149			120-129	111-119	≤ 110	
Serum Potassium (mMol/L)	APCH108	6-6.9			5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		< 2.5	

RSTESTCD	RSTEST	RSCAT	RSORRES	RSORRESU	RSSTRESC	RSSTRESN
APCH101	APCH1-Temperature - Rectal	APACHE II	38.5-38.9	C	1	1
APCH102	APCH1-Mean Arterial Pressure	APACHE II	110-129	mmHg	2	2
APCH103	APCH1-Heart Rate	APACHE II	70-109	beats/min	0	0
APCH104	APCH1-Respiratory Rate	APACHE II	>=50	breaths/min	4	4
APCH105A	APCH1-Oxygenation: A-aDO ₂	APACHE II				
APCH105B	APCH1-Oxygenation: PaO ₂	APACHE II	61-70	mmHg	1	1
APCH106A	APCH1-Arterial pH	APACHE II	<7.15		4	4
APCH106B	APCH1-Serum HCO ₃	APACHE II				
APCH107	APCH1-Serum Sodium	APACHE II	150-154	mmol/L	1	1
APCH108	APCH1-Serum Potassium	APACHE II	3.5-5.4	mmol/L	0	0

Units are included in the pre-defined responses, --ORRESU/--STRESU are null

Parameter	0 Points	1 Point	2 Points
Age	< 60 years	60 - 79 years	>= 80 years
Treatment with systemic antibiotics during CDI therapy (>= 1 day)	No		Yes
Leukocyte count (total)	< 16,000	16,000 - 25,000	>25,000
Albumin (serum)	>35 g/L	26 - 35 g/L	<= 25 g/L
Serum creatinine (as a measure of renal function)	<= 120 umol/L	121 - 179 umol/L	>= 180 umol/L

RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSSTRESN
ATLAS101	ATLAS1-Age	ATLAS	60-79 years	1	1
ATLAS102	ATLAS1-Treatment With Antibiotics	ATLAS	Yes	2	2
ATLAS103	ATLAS1-Leukocyte Count	ATLAS	< 16,000	0	0
ATLAS104	ATLAS1-Albumin	ATLAS	26 - 35 g/L	1	1
ATLAS105	ATLAS1-Serum Creatinine	ATLAS	>= 180 umol/L	2	2
ATLAS106	ATLAS1-Score	ATLAS	6	6	6



CD

Total Score and Sub-total Score

- Subtotal and total scores are represented in --ORRES, --STRESC, and --STRESN
- If scores are received or derived by the sponsor, it is recommended that they are submitted to SDTM and verified in ADaM whenever feasible.
- Details could be documented in SDRG and ADRG.

About --DRVFL

Concept aligned in 2018

Scenario	--DRVFL (derived flag)
Derived by the sponsor in EDC	Y (ORESS could be null)
Investigator calculate the score and written on a CRF	<null>
Received from external data supplier	<null>

Upcoming changes:

The SDS team is considering to deprecate the --DRVFL variable in SDTMIG V4.0.

CDISC QRS has stopped using it, all derived data are considered as captured data moving forward.

--LOC, --LAT and --DIR

- QRS --TEST/CDs and definitions must be verbatim to how they appear on the “standard” QRS instruments. The pre-specified anatomical locations that appear on the instrument need to be pre-coordinated into the QRS --TEST-CDs and described in the definitions **AS THEY ARE**.
- Location, Laterality, Directionality (--LOC, --DIR, --LAT) values controlled by CTs shall NOT be used in general because they may look different from the instrument.

rs.xpt

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSSCAT	RSORRES	RSSTRESC	RSSTRESN	RSSTAT	VISITNUM	RSDTC
1	STUDYX	RS	P0001	1	AIMS0101	AIMS01-Muscles of Facial Expression	AIMS	FACIAL AND ORAL MOVEMENTS	Minimal, may be extreme normal	1	1		2	
2	STUDYX	RS	P0001	2	AIMS0102	AIMS01-Lips and Perioral Area	AIMS	FACIAL AND ORAL MOVEMENTS	None	0	0		2	2013-04-18
3	STUDYX	RS	P0001	3	AIMS0103	AIMS01-Jaw	AIMS	FACIAL AND ORAL MOVEMENTS	Mild	2	2		2	2013-04-18
4	STUDYX	RS	P0001	4	AIMS0104	AIMS01-Tongue	AIMS	FACIAL AND ORAL MOVEMENTS	Moderate	3	3		2	2013-04-18
5	STUDYX	RS	P0001	5	AIMS0105	AIMS01-Upper Extremities	AIMS	EXTREMITY MOVEMENTS	Severe	4	4		2	2013-04-18
6	STUDYX	RS	P0001	6	AIMS0106	AIMS01-Lower Extremities	AIMS	EXTREMITY MOVEMENTS	Mild	2	2		2	2013-04-18

Exception: Instrument without standard CRF

Example: Pain Intensity (PI)

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN	QSLOC	QSLAT	QSMETHOD	VISITNUM	QSDTC	QSDY	QSEVLINT
1	STUDYX	QS	2324-P0002	1	PI0105	PI01-Least Pain Intensity	PI	DIABETIC PERIPHERAL NEUROPATHY PAIN	SEVERE	3	3	FOOT	RIGHT	VERBAL RATING SCALE 4-POINT	1	2004-01-03	1	-PT24H
2	STUDYX	QS	2324-P0002	2	PI0105	PI01-Least Pain Intensity	PI	DIABETIC PERIPHERAL NEUROPATHY PAIN	MODERATE	2	2	FOOT	RIGHT	VERBAL RATING SCALE 4-POINT	2	2004-01-09	7	-PT24H
3	STUDYX	QS	2324-P0002	3	PI0105	PI01-Least Pain Intensity	PI	DIABETIC PERIPHERAL NEUROPATHY PAIN	MILD	1	1	FOOT	RIGHT	VERBAL RATING SCALE 4-POINT	3	2004-01-16	14	-PT24H

When --ORRES >200 characters

Pre-defined response > 200 characters

<i>Answer for Actual Attempts Only</i>			
Actual Lethality/Medical Damage:			
0. No physical damage or very minor physical damage (e.g., surface scratches).			
1. Minor physical damage (e.g., lethargic speech).	Selected on the instrument (>200 character)	QSORRES in mapping (shortened <=200 character)	QSSTRES- /QSSTRESN
2. Moderate physical damage; medical attention required (e.g., lacerations; burns; bleeding of major vessel).	Moderately severe physical damage; medical hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures)	Moderately severe physical damage; medical hospitalization and likely intensive care required	3
3. Moderately severe physical damage; medical attention required (e.g., lacerations; burns; bleeding of major vessel); <i>medical attention required</i> ; third-degree burns less than 20% of body.			
4. Severe physical damage; <i>medical attention required</i> ; third-degree burns over 20% of body; extensive blood loss; major fractures.	Severe physical damage; medical hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area)	Severe physical damage; medical hospitalization with intensive care required	4
5. Death			

Free-text response >200 characters for field with --TEST CD assigned

SUICIDAL IDEATION		
<i>Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.</i>		Prior to Study Entry: Time He/She Felt Most Suicidal
1. Wish to be Dead Subject endorses thoughts about a wish to be dead or not alive. <i>Have you wished you were dead or wished you could go to death?</i>	Inappropriate to use the "shorten" approach. Additional text could be stored in SUPP.	Since Study Start:
If yes, describe:		Yes <input type="checkbox"/> No <input type="checkbox"/>

VAS

--METHOD

VISUAL ANALOG SCALE (0-100)

VISUAL ANALOG SCALE (1-10)

VISUAL ANALOG SCALE (1-100)

VISUAL ANALOG SCALE (1-50)

VISUAL ANALOG SCALE (10 CM)

VISUAL ANALOG SCALE (100 MM)

VISUAL ANALOG SCALE (50 MM)

Note:

Terms with length units shall be used **only if** the VAS line is required as exactly 10cm, 100mm, 50mm on the VAS instrument



- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine. 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale below.

VISUAL ANALOG SCALE (0-100) ✓

VISUAL ANALOG SCALE (100 MM) ✗

QSTESTCD = EQ5D0206
YOUR HEALTH TODAY =

QSORRES

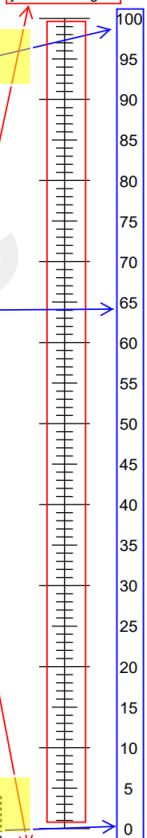
QSSTRESC/QSSTRESN

QSEVINTX = TODAY

QSANVLHI
in SUPPQS

QSANTXHI
in SUPPOS

The best health
you can imagine



The worst health
you can imagine

QSANTXLO
in SUPPOS

SUPP: Anchor High/Low

ANTXHI
(Anchor Text High)

ANTXLO
(Anchor Text Low)

ANVLHI
(Anchor Numeric Value High)

ANVLLLO
(Anchor Numeric Value Low)

Do Not Use --EVAL / --EVALID

For QRS, evaluator is rarely collected on CRF, and it's not called "evaluator". For example, EPDS has "Administered/Reviewed by"; ADCS-ADL MCI has "Examiner initials"; DAD has "Respondent" and "Rater"; "DRS has "Name of Person Completing Form"; etc. If --EVAL is used, there is difficulty to know what it truly means.

- ✓ Administrative information shall be presented in SDTM dataset only if it is explicitly collected on an instrument.
- ✓ Some QRS specific Non-Standard Variables (NSVs) represent collected administrator or respondent details, which are captured in SUPP domains.

Example: "COLAID" for "Collected Administrator Identifier"

Domain	SUPP QNAM	SUPP QLABEL
QS	QSCOLAID	Collected Administrator Identifier
FT	FTCOLAID	Collected Administrator Identifier
RS	RSCOLAID	Collected Administrator Identifier

QRS Supplemental Variables

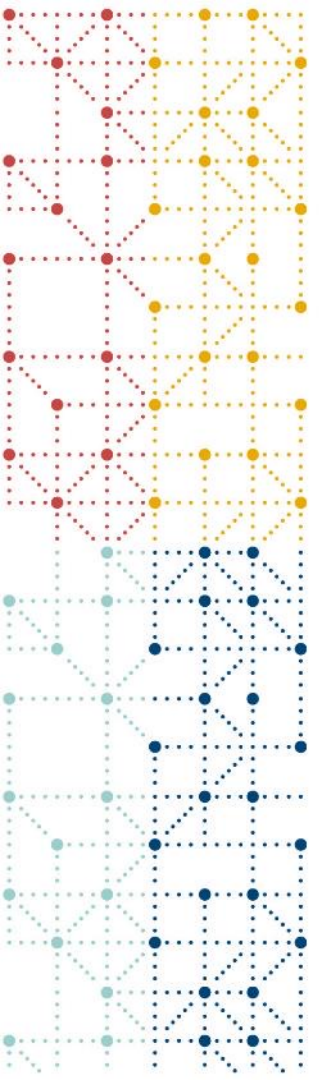
All QRS supplemental qualifier variables (SUPPQUAL) have been reviewed to meet the current NSV naming rules. [QRS NSV Registry FT QS RS Summary](#) contains the list of existing QRS SUPPQUAL variable along with the new SUPPQUAL(NSV) name included in the NSV Registry.

When using a QRS supplement that includes QRS suppqual variables, users need to reference the [QRS NSV Registry FT QS RS Summary](#) and use the current NSV Registry variables.



QRS NSV
Summary

Future changes: QRS supplemental QNAM/QLABEL values will be turned into QXPARM-CDs in the SDTMIG v4.0. Data will be stored in the QX domain.



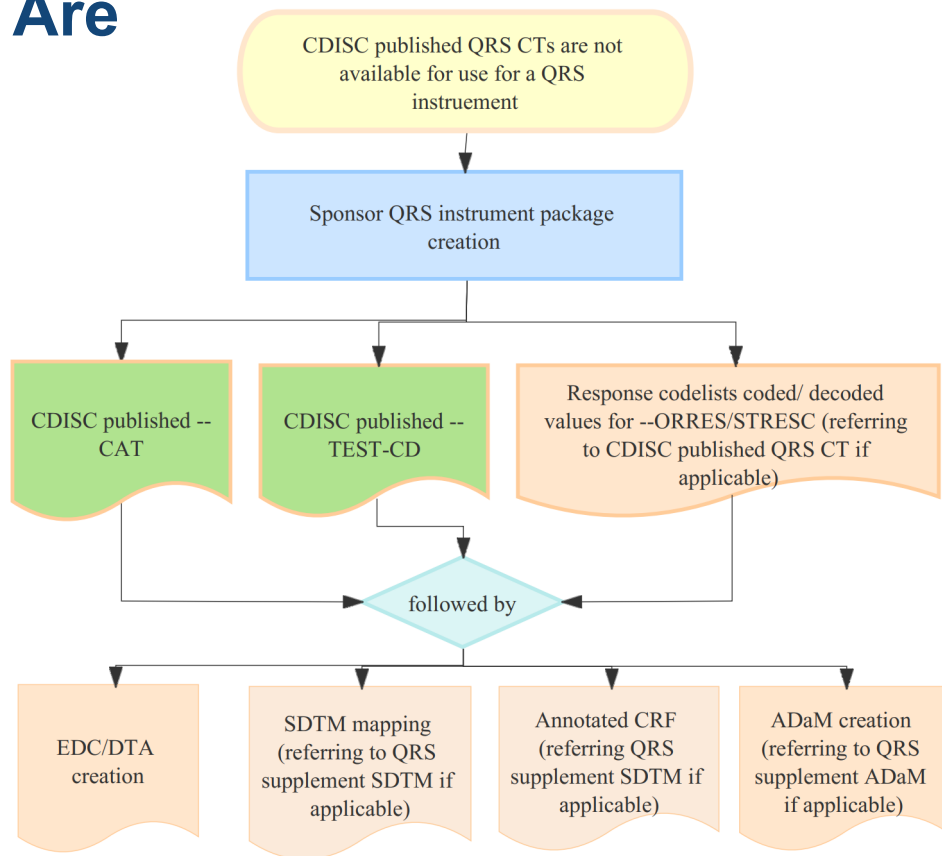
QRS – Sponsor QRS Metadata

CDISC Published QRS CTs Are Available For Use

The most important components would be --CAT and --TEST-CD.

--CAT definition shall be checked to ensure the same QRS instrument correct version is referred to. If not sponsor-specific custom CTs shall be created.

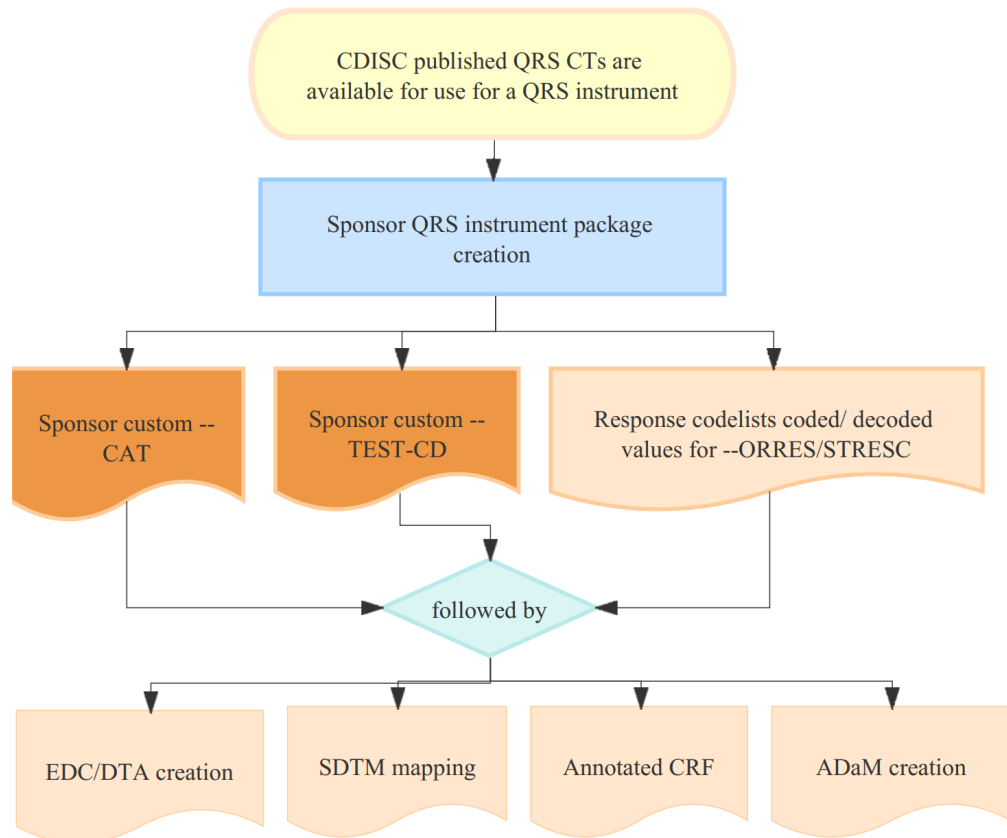
Sponsor can decide how to use the ORRES/STRESC codelists. For example, sponsor can choose to include ORRES and corresponding STRESC values in the same codelist as decoded/coded (or reversed) values for EDC setup.



CDISC Published QRS CTs are **Not** Available For Use

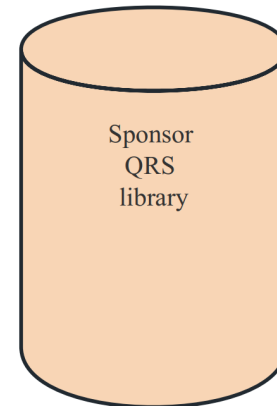
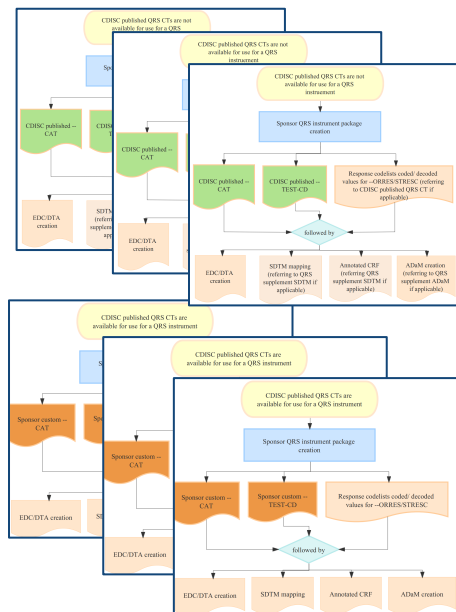
Due to the large number of QRS and its wider use in clinical trials, people may find that plenty of QRS instruments used in clinical trials are not covered by CDISC published QRS CTs.

- ◆ *Sponsor-specific custom QRS package will need to be created following QRS general rules and naming conventions.*
- ◆ *Could mimic CDISC published QRS CTs for sponsor-specific QRS CTs creation, but it is recommended to have sponsor-specific identifiers to differentiate the sponsor-specific QRS CTs and CDISC published QRS CTs.*

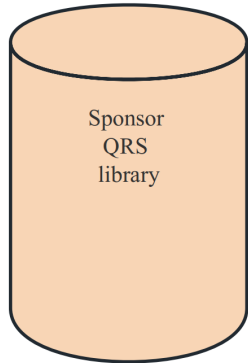


Sponsor QRS Library

Dozens or hundreds of standard QRS instruments could be commonly used/re-used by a sponsor depends on the pipeline in different therapeutic areas. A well maintained QRS library at sponsor will be very helpful to reduce repetition work and improve data quality and compliance.

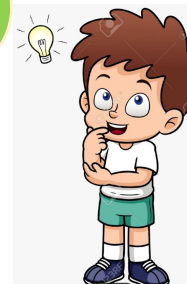


Sponsor QRS Library



- ◆ QRS catalogue for QRS instruments and versions
- ◆ Clear definitions and version control for better tracking
- ◆ Easily differentiate sponsor custom CTs and CDISC published QRS CTs
- ◆ SDTM CT shall be maintained in a way that enable easy data collection system setup (EDC QRS form for internal QRS, and DTA for external QRS), SDTM transformation, and other downstream work
- ◆ ...

QRS-specific
Code Table



Abnormal Involuntary Movement Scale (AIMS)

Code	Code/Code	Code/Code	Code/Code	Code/Code	Code/Code	Code/Code
C118971		Category of Clinical Classification	CCCAT	Category of Clinical Classification	A grouping of observations within the Disease Response and Clinical Classification domain.	CDISC Clinical Classification Category Terminology
C102111	C118971	Category of Clinical Classification	AIMS	AIMS01	Abnormal Involuntary Movement Scale (AIMS) (Guy W. Ed. ECDEU Assessment Manual for Psychopharmacology, Rockville MD: US Dept of Health, Education and Welfare, 1976; Publication No. (ADM) 76-739)	Abnormal Involuntary Movement Scale Clinical Classification

C101805	Abnormal Involuntary Movement Scale Clinical Classification Test Code	AIMS01TC	Abnormal Involuntary Movement Scale Clinical Classification Test Code	Abnormal Involuntary Movement Scale test code	CDISC Clinical Classification AIMS Test Code Terminology
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C101806	Abnormal Involuntary Movement Scale Clinical Classification Test Name	AIMS01TN	Abnormal Involuntary Movement Scale Clinical Classification Test Name	Abnormal Involuntary Movement Scale test name.	CDISC Clinical Classification AIMS Test Name Terminology
C102044	C182464	Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	AIMS0101T07OR	Abnormal Involuntary Movement Scale Clinical Classification ORRES for AIMS0101 Through AIMS0107 TN/TC	CDISC Clinical Classification Abnormal Involuntary Movement Scale AIMS0101 Through AIMS0107 Original Response Terminology
C102042	C182674	Abnormal Involuntary Movement Scale	AIMS0101 through AIMS0107	Abnormal Involuntary Movement Scale original result for AIMS0101	Abnormal Involuntary Movement Scale AIMS0101
C102036	C182466	Abnormal Involuntary Movement Scale Clinical Classification ORRES for	AIMS0110OR	Abnormal Involuntary Movement Scale Clinical Classification	CDISC Clinical Classification Abnormal Involuntary Movement Scale AIMS0110 Original Response Terminology
C182502		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	AIMS0101T07STR	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	CDISC Clinical Classification Abnormal Involuntary Movement Scale AIMS0101 Through AIMS0107 Standardized Character Response Terminology
C182677	C182502	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	0 AIMS0101 through AIMS0107-0	Abnormal Involuntary Movement Scale standardized character result for AIMS0101 through AIMS0107-None.	Abnormal Involuntary Movement Scale AIMS0101 Through AIMS0107 Standardized Character Result 0
C182678	C182502	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	1 AIMS0101 through AIMS0107-1	Abnormal Involuntary Movement Scale standardized character result for AIMS0101 through AIMS0107-Minimal, may be extreme normal.	Abnormal Involuntary Movement Scale AIMS0101 Through AIMS0107 Standardized Character Result 1
C182679	C182502	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0101 Through AIMS0107 TN/TC	2 AIMS0101 through AIMS0107-2	Abnormal Involuntary Movement Scale standardized character result for AIMS0101 through AIMS0107-Mild.	Abnormal Involuntary Movement Scale AIMS0101 Through AIMS0107 Standardized Character Result 2
C182504		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	AIMS0110STR	Abnormal Involuntary Movement Scale standardized character result for AIMS0110 test and test code.	CDISC Clinical Classification Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Response Terminology
C182697	C182504	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	0 AIMS0110-0	Abnormal Involuntary Movement Scale standardized character result for AIMS0110-No awareness.	Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Result 0
C182698	C182504	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	1 AIMS0110-1	Abnormal Involuntary Movement Scale standardized character result for AIMS0110-Aware, no distress.	Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Result 1
C182699	C182504	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	2 AIMS0110-2	Abnormal Involuntary Movement Scale standardized character result for AIMS0110-Aware, mild distress.	Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Result 2
C182700	C182504	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	3 AIMS0110-3	Abnormal Involuntary Movement Scale standardized character result for AIMS0110-Aware, moderate distress.	Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Result 3
C182701	C182504	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0110 TN/TC	4 AIMS0110-4	Abnormal Involuntary Movement Scale standardized character result for AIMS0110-Aware, severe distress.	Abnormal Involuntary Movement Scale AIMS0110 Standardized Character Result 4
C182505		Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0111 Through AIMS0112 TN/TC	AIMS011112STR	Abnormal Involuntary Movement Scale standardized character result for AIMS0111 through AIMS0112 test and test code.	CDISC Clinical Classification Abnormal Involuntary Movement Scale AIMS0111 Through AIMS0112 Standardized Character Response Terminology
C182704	C182505	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0111 Through AIMS0112 TN/TC	0 AIMS0111 through AIMS0112-0	Abnormal Involuntary Movement Scale standardized character result for AIMS0111 through AIMS0112-No	Abnormal Involuntary Movement Scale AIMS0111 Through AIMS0112 Standardized Character Result 0
C182705	C182505	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0111 Through AIMS0112 TN/TC	1 AIMS0111 through AIMS0112-1	Abnormal Involuntary Movement Scale standardized character result for AIMS0111 through AIMS0112-Yes.	Abnormal Involuntary Movement Scale AIMS0111 through AIMS0112 Standardized Character Result 1
C182691	C182503	Abnormal Involuntary Movement Scale Clinical Classification STRESC for AIMS0108 Through AIMS0109 TN/TC	4 AIMS0108 through AIMS0109-4	Abnormal Involuntary Movement Scale standardized character result for AIMS0108 through AIMS0109-Severe.	Abnormal Involuntary Movement Scale AIMS0108 Through AIMS0109 Standardized Character Result 4

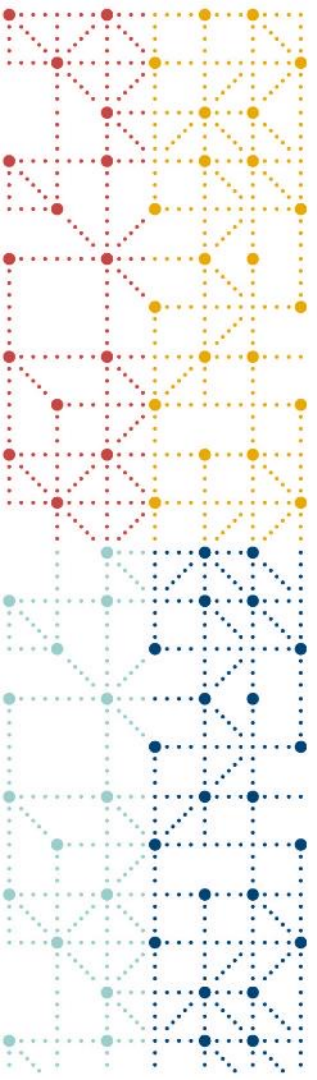
AIMS Code Table

Instrument	Abnormal Involuntary Movement Scale (AIMS)										
Category	CCCAT = AIMS (Synonym=AIMS01)										
Definition	Abnormal Involuntary Movement Scale (AIMS) (Guy W. Ed. ECDEU Assessment Manual for Psychopharmacology. Rockville MD: US Dept of Health, Education and Welfare. 1976, Publication No. (ADM) 76-338). CDISC believes this instrument to be in the public domain, but you should perform your own assessment.										
Field	RSTESTCD	RSTEST	RSSCAT	RSMETHOD	RSORRES	RSORRESU	RSSTRESC	RSSTRESCU	RSSTRESI	<SP-QNAM	<SP-QLABEL
1	AIMS0101	AIMS01-Muscles of Facial Expression	FACIAL AND ORAL MOVEMENTS	<null>	None		0		0		
1					Minimal, may be extreme normal		1		1		
1					Mild		2		2		
1					Moderate		3		3		
1					Severe		4		4		
2	AIMS0102	AIMS01-Lips and Perioral Area	FACIAL AND ORAL MOVEMENTS	<null>	None		0		0		
2					Minimal, may be extreme normal		1		1		
2					Mild		2		2		
2					Moderate		3		3		
2					Severe		4		4		

- ◆ One code table for one version of QRS instrument.
- ◆ Except --CAT, --TEST-CD, --ORRES, and --STRESC, other fields, for example, --METHOD, --SCAT, --ORRESU, --STRESU, and supplemental variables if applicable, are all included in one code table.
- ◆ Annotated CRF can be maintained together with the code table

Example of How to Use QRS Code Table

- ◆ EDC QRS form setup
 - ✓ *EDC FormOID (come from QRS category)*
 - ✓ *EDC Form Name (QRS full name with abbreviation)*
 - ✓ *EDC FieldOID (come from Test Code)*
 - ✓ *EDC Field Label (come from Test Name)*
 - ✓ *Codelists attached to the fields (--ORRES/--STRESC set up as decoded/coded values)*
 - ✓ *EDC FieldOID for Supplemental variable (come from QNAM)*
 - ✓ *EDC Field Label for Supplemental variable (come from QLABEL)*
- ◆ DTA preparation
 - ✓ *Code table can be provided to data supplier as QRS data transfer specification*
- ◆ SDTM mapping specifications
 - ✓ *Codetable shall be a very good reference*
- ◆ Other applicable



A special thanks to Steve and Jordan from CDISC QRS team!

Thank You!

