

Using CDISC QRS Supplements for the implementation of eCOA

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Agenda

- What is eCOA?
- How CDISC QRS relates to eCOA
- What is included in a QRS Supplement
- QRS Domains: RS, FT, QS
- Terminology Rules for QS, FT
- Clincase ePRO Demo Study

What is COA (Clinical Outcome Assessment)?

There are different types of COAs:

PRO

Directly from patient

ClinRO

From healthcare professional observing patient

ObsRO

Someone other than patient or healthcare professional

PerfO

Standardized task by trained individual

How CDISC QRS relates to eCOA

CDISC QRS Supplements assist in structuring eCOA data so that it is collected and reported in a standardized format

CDISC SDTM QRS Supplements	FDA COA			
	ClinRO	ObsRO	PRO	PerfO
Questionnaires	X	X	X	
Functional tests				X
Clinical Classifications	X	X		

What is included in CDISC QRS Instruments?

QRS supplements to the SDTMIG and ADaMIG include

- Controlled Terminology
- SDTM
- ADaM
- CDASH

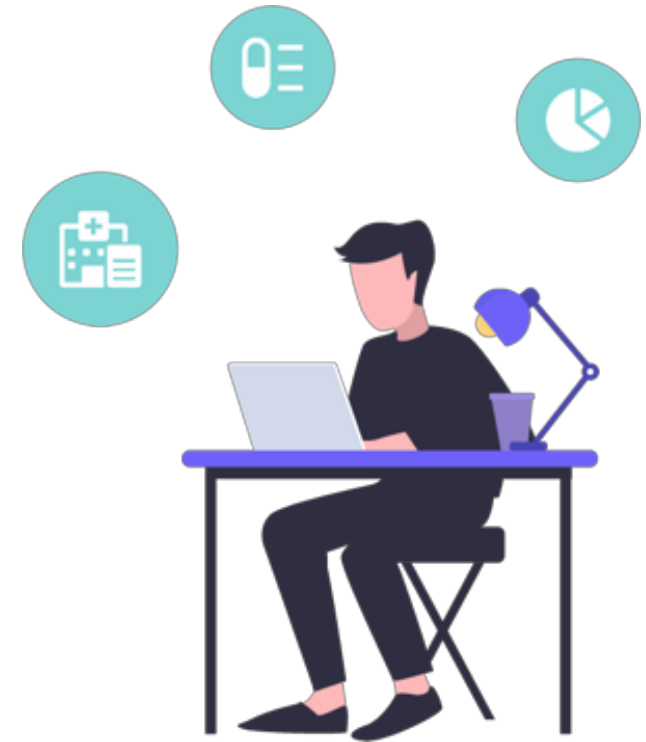
QRS contains a eCRF and guidance for mapping to the CDISC standards



FDA Clinical Outcome Assessment (COA) Qualification Program

FDA qualifies COA Instruments to encourage their usage. Some questionnaires are already qualified. Many more now in the process of qualification and should be added soon.

Qualified COA Instruments are supplemented by CDISC QRS

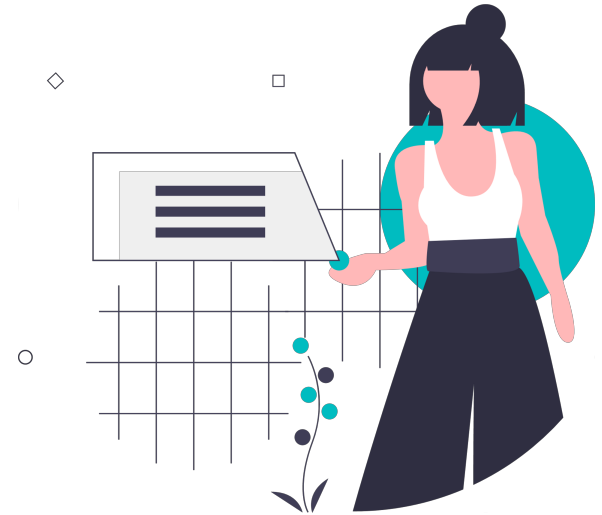


CDISC QRS: RS, FT, QS

CDISC QRS Supplements consist of three types of instruments:

1. Questionnaires (QS)
2. Functional Tests (FT)
3. Clinical Classification (RS)

FT and RS are introduced with SDTMIG
3.3



Questionnaires (QS)

- Defined standard structure, format, and content
- Defined questions with a defined set of potential answers
- Generates qualitative statistics to assess a qualitative concept



Questionnaires (QS) Examples

QS=Questionnaires

QSCAT=SWLS

Below are five statements that you may agree or disagree with. Using the 1 - 7 scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding.

QSSSTRESC/QSSSTRESN

- 7 - Strongly agree
- 6 - Agree
- 5 - Slightly agree
- 4 - Neither agree nor disagree
- 3 - Slightly disagree
- 2 - Disagree
- 1 - Strongly disagree

QSORRES

___ In most ways my life is close to my ideal. **QSTESTCD = SWLS0101**

___ The conditions of my life are excellent. **QSTESTCD = SWLS0102**

___ I am satisfied with my life. **QSTESTCD = SWLS0103**

___ So far I have gotten the important things I want in life. **QSTESTCD = SWLS0104**

___ If I could live my life over, I would change almost nothing. **QSTESTCD = SWLS0105**

Questionnaires (QS) Examples

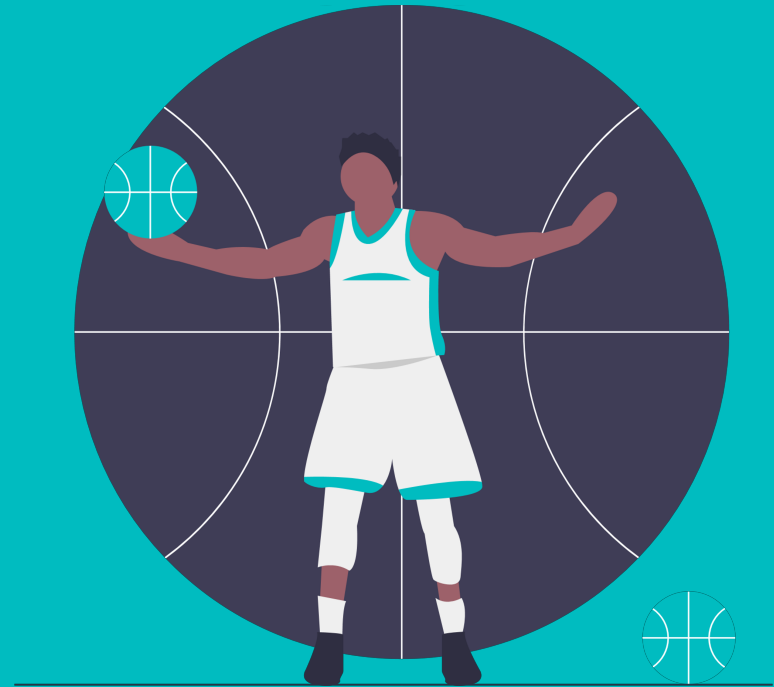
Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	P0001	1	SWLS0101	SWLS01-My Life is Close to Ideal	SWLS	Slightly agree	5	5
2	STUDYX	QS	P0001	2	SWLS0102	SWLS01-My Life Conditions are Excellent	SWLS	Neither agree nor disagree	4	4
3	STUDYX	QS	P0001	3	SWLS0103	SWLS01-I Am Satisfied with My Life	SWLS	Agree	6	6
4	STUDYX	QS	P0001	4	SWLS0104	SWLS01-Have Gotten Important Things	SWLS	Disagree	2	2
5	STUDYX	QS	P0001	5	SWLS0105	SWLS01-Live Life Over Change Nothing	SWLS	Strongly disagree	1	1

(contd.
columns)

QSCAT	QSORRES	QSSTRESC	QSSTRESN
SWLS	Slightly agree	5	5
SWLS	Neither agree nor disagree	4	4
SWLS	Agree	6	6
SWLS	Disagree	2	2
SWLS	Strongly disagree	1	1

Functional Test (FT)

- Are named, standalone task-based evaluations
- An objective direct measurement of the performance of the task by the subject in a specific instance
- Have documented methods for administration and analysis



Functional Test (FT) example

FT=Functional Tests

FTCAT=SIX MINUTE WALK

Date: **FTDTC** _____

Subject: _____

Assisted Device: **QVAL when QNAM=FTASSTDV** _____

6 Minute Walk Test

	Cumulative Distance
Distance at 1 minute FTTESTCD=SIXMW101	← FTORRES
Distance at 2 minutes FTTESTCD=SIXMW102	
Distance at 3 minutes FTTESTCD=SIXMW103	
Distance at 4 minutes FTTESTCD=SIXMW104	
Distance at 5 minutes FTTESTCD=SIXMW105	
Distance at 6 minutes FTTESTCD=SIXMW106	

Functional Test (FT) example

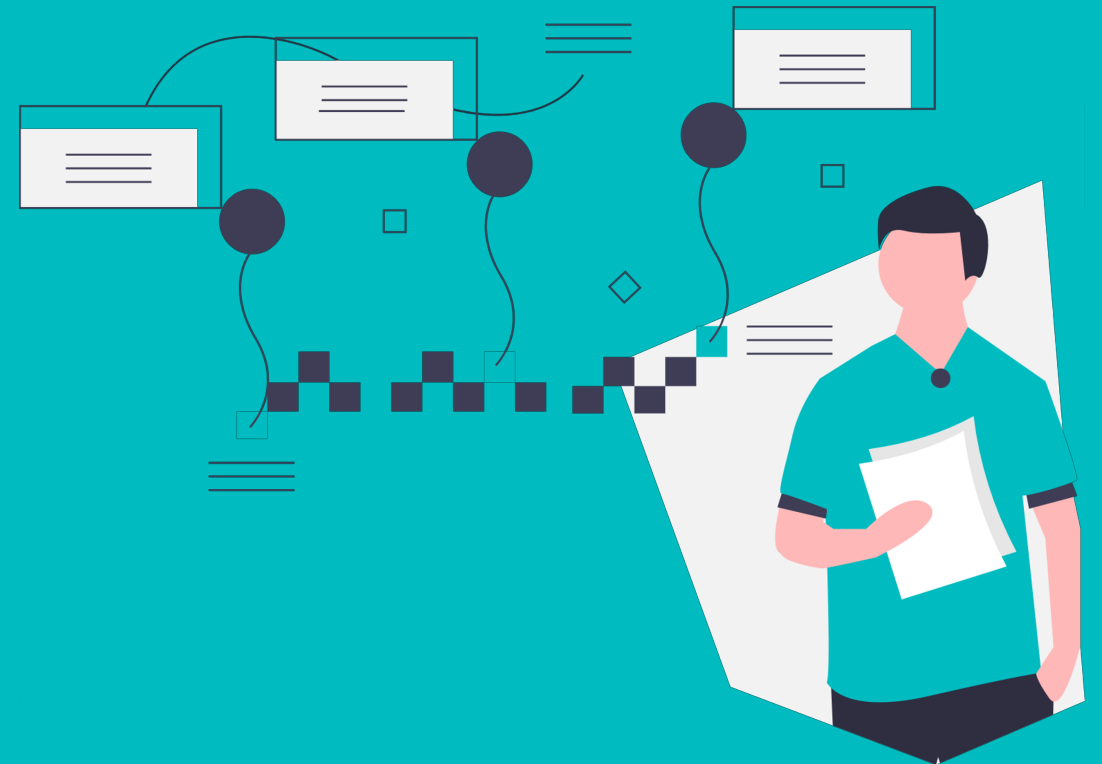
Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN
1	STUDYX	FT	MS01-01	1	1	SIXMW101	SIXMW1-Distance at 1 Minute	SIX MINUTE WALK	101	m	101	101
2	STUDYX	FT	MS01-01	2	1	SIXMW102	SIXMW1-Distance at 2 Minutes	SIX MINUTE WALK	201	m	201	201
3	STUDYX	FT	MS01-01	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

(contd.
columns)

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

Clinical Classifications (RS)

- related to multiple body systems
- based on a trained healthcare professional's observation
- often composite scores based on diverse inputs



Clinical Classifications (RS) example

RS=Disease Response and Clin Classification

B rooke Upper Extremity Rating Scale

RSTESTCD=BUERS101

RSCAT=BUERS

	Grade	RSORRES	Description
RSSTRESC/ RSSTRESN	1		Starting with arms at the sides, the patient can abduct the arms in a full circle until they touch above the head. *
	2		Can raise arms above head only by flexing the elbow (shortening the circumference of the movement) or using accessory muscles.*
	3		Cannot raise hands above head, but can raise an 8-oz glass of water to the mouth.
	4		Can raise hands to the mouth, but cannot raise an 8-oz glass of water to the mouth.
	5		Cannot raise hands to the mouth, but can use hands to hold a pen or pick up pennies from the table.
	6		Cannot raise hands to the mouth and has no useful function of hands.

Clinical Classifications (RS) example

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC
1	1001	RS	1001-001	1	BUERS101	BUERS1-Brooke Upper Extremity Rating	BUERS	Cannot raise hands above head, but can raise an 8-oz glass of water to the mouth.	3
2	1001	RS	1001-002	1	BUERS101	BUERS1-Brooke Upper Extremity Rating	BUERS	Starting with arms at the sides, the patient can abduct the arms in a full circle until they touch above the head.	1

(contd.
columns)

Row	RSSTRESN	RSBLFL	RSEVAL	VISITNUM	VISIT	RSDTC
1 (cont)	3	Y	INVESTIGATOR	1	Visit 1	2012-05-10
2 (cont)	1	Y	INVESTIGATOR	1	Visit 1	2012-10-08

Terminology Rules for QS, FT

US English is the strongly preferred language for QRS terminology.

The main rule: always use English as a core language even if you conduct a study in another local language



Terminology Rules for QS, FT example

- d. Evening
- 4. How many cups of coffee do you drink per day?
1,2,3,4,5
- 5. Do you prefer going out for coffee or drinking it at home?
 - a. Going out
 - b. Drinking at home
- 6. What type of coffee do you usually drink or buy?
 - a. Espresso
 - b. Americano
 - c. Cappuccino
 - d. Mocha
 - e. Latte/Café Latte
 - f. Macchiato
 - g. Ristretto
 - h. Iced coffee
 - i. Nitro coffee
- 7. When you make coffee at home, please specify which kind you make?
 - a. Espresso machine

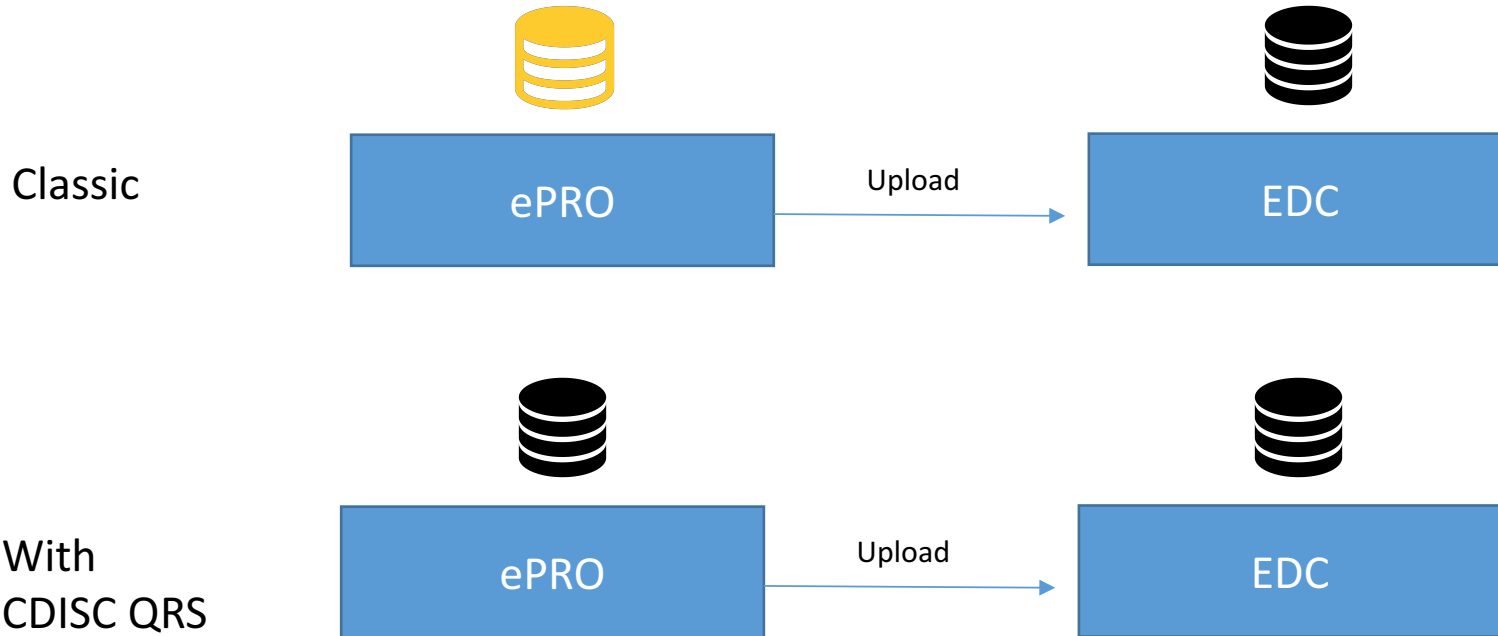
Terminology Rules for QS, FT example

The screenshot displays a software interface for managing questionnaire items. On the left, a sidebar titled 'Items' lists various data types: Text, Numeric, Date, Time, Timestamp, Group, Lab Group, Set, Label, Image Map, File Upload, and Action Label. The main area shows a list of items under the heading 'DairyQuestionnaire'. A red box highlights a specific section of the list, including the following items:

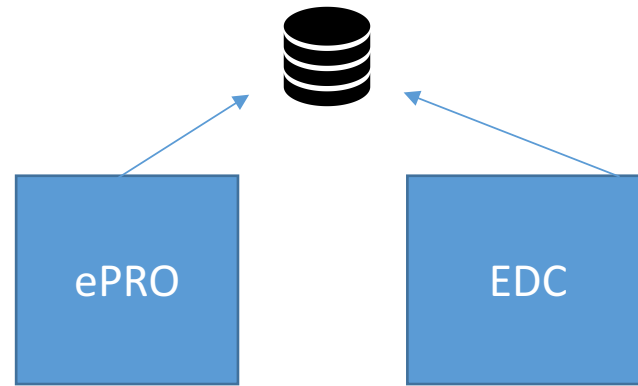
- Name: question4_demo Label: How Many Cups Do You Drink per Day? Type: Numeric
- Name: question5_demo Label: Do You Prefer Going out/Drinking It at Home?
- Name: question5_1_demo Label: Do You Prefer Going out/Drinking It at Home? Type: Nu
- Name: question6_demo Label: What Type of Coffee Do You Drink/Buy?
- Name: ESPRESSO Label: ESPRESSO Type: Numeric Code List: 1=YES 2=NO
- Name: AMERICANO Label: AMERICANO Type: Numeric Code List: 1=YES 2=NO
- Name: CAPPUCINO Label: CAPPUCINO Type: Numeric Code List: 1=YES 2=NO
- Name: MOCHA Label: MOCHA Type: Numeric Code List: 1=YES 2=NO
- Name: LATTE Label: LATTE/CAFE LATTE Type: Numeric Code List: 1=YES 2=NO

At the bottom of the interface, there are tabs for 'Layout', 'Schema', and 'XML Source'. Below these, there are buttons for 'Form Preview', 'Schema Map', and 'Reports'. The bottom-most part of the image shows the beginning of a section labeled 'eDiary'.

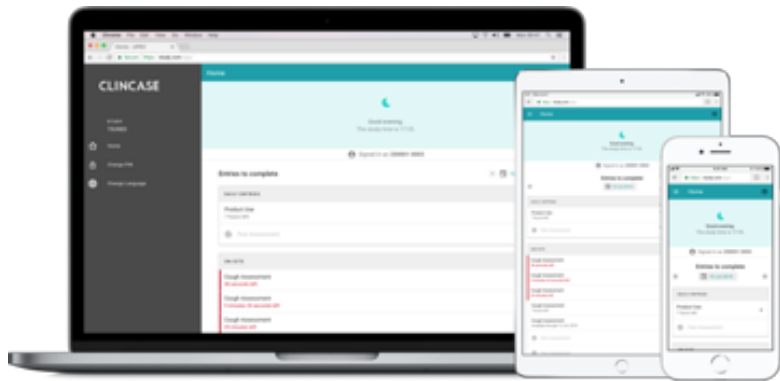
EPRO and EDC – Same Standards?



EPRO and EDC – New Approach



Demo Study



Step into a Subject's shoes:
see how ePRO works.

Join us at the coffee break!



