

German CDISC User Group Meeting

Questionnaire CT Concept FAQ

QSTEST/QSTESTCD vs LBTEST/LBTESTCD

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C67154		Yes	Laboratory Test Name	LBTEST	Laboratory Test Name
C65047		Yes	Laboratory Test Code	LBTESTCD	Laboratory Test Code
C64471	C65047		Laboratory Test Code	BASOLE	Basophils/Leukocytes
C64471	C67154		Laboratory Test Name	Basophils/Leukocytes	Basophils/Leukocytes
C38037	C65047		Laboratory Test Code	BILI	Bilirubin; Total Bilirubin
C38037	C67154		Laboratory Test Name	Bilirubin	Bilirubin; Total Bilirubin

LBTEST

LBTESTCD

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C100169		No	QS-Karnofsky Performance Status Scale Test Name	KPS Scale TEST	QS-Karnofsky Performance Status Scale Test Name
C100170		No	QS-Karnofsky Performance Status Scale Test Code	KPS Scale TESTCD	QS-Karnofsky Performance Status Scale Test Code
C100417	C100170		QS-Karnofsky Performance Status Scale Test Code	KPSS01	KPSS-Karnofsky Performance Status
C100417	C100169		QS-Karnofsky Performance Status Scale Test Name	KPSS-Karnofsky Performance Status	KPSS-Karnofsky Performance Status
C120988		No	CC-Child-Pugh Clinical Classification Test Name	CHILD-PUGH CLASSIFICATION TEST	CC-Child-Pugh Clinical Classification Test Name
C120989		No	CC-Child-Pugh Clinical Classification Test Code	CHILD-PUGH CLASSIFICATION TESTCD	CC-Child-Pugh Clinical Classification Test Code
C121068	C120989		CC-Child-Pugh Clinical Classification Test Code	CPS0101	CPS01-Encephalopathy Grade
C121068	C120988		CC-Child-Pugh Clinical Classification Test Name	CPS01-Encephalopathy Grade	CPS01-Encephalopathy Grade

QSTEST

QSTESTCD

Special:
QSTEST / QSTESTCD
Code different for each
distinct Questionnaire

As is... (in define.xml v1.0 up to ODM 1.3.2)

No NCI Code reference required for QSTEST/QSTESTCD in define.xml (v1.0)!

- Questionnaires can be represented as all other --TEST/--TESTCD's via...

VLM

Value Level Metadata (ValueList.QS.QSCAT.CS.QSTESTCD)						
Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Comment
CSDD	CSDD01	Anxiety	integer	CUE EXPF X	CRF Page 14	
CSDD	CSDD02	Sadness	integer	CUE EXPF X	CRF Page 14	
CSDD	CSDD03	Lack of Reactivity to Pleasant Events	integer	CUE EXPF X	CRF Page 14	
CSDD	CSDD04	Irritability	integer	CUE EXPF X	CRF Page 14	
CSDD	CSDD05	Agitation	integer	CUE EXPF X	CRF Page 14	

or

CT

QSTESTCD, Reference Name (QSTESTCD)	
Code Value	Code Text
CSDD01	Anxiety
CSDD02	Sadness
CSDD03	Lack of Reactivity to Pleasant Events
CSDD04	Irritability
CSDD05	Agitation

So far so good, but...

How will you represent QSTEST/QSTESTCD in define.xml (v2.0)?

- As existing NCI Codes should be added, is there any negative impact because there is no unique NCI reference code for QSTEST/QSTESTCD as is in SDTM CT e.g. for LBTEST/LBTESTCD?
- Will it be required to include QSTEST and QSTESTCD NCI code values as defined or will it be „optional“, to be decided case by case for each CT?
E.g. NCI codes for Questionnaires CT (QSTEST + QSTESTCD) omitted in define-2-0.xml example (see next slides)
- There is an expected impact on validation tools for the define.xml v2.0 or is this special case for QS CT (multiple codes for QSTEST and QSTESTCD possible) well known by the ODM Team? Are checks for QSTEST and QSTESTCD different to other CT's and is it possible to define multiple alias links for them and referring to QRS Codelist?

Define.xml v2.0 Example

Codelists as expected with corresponding NCI code values

- ▼ Controlled Terminology
 - ▼ Controlled Terms
 - Action Taken with Study Treatment
 - Domain Abbreviation (AE)
 - Relation to Reference Period (AE)
 - Causality
 - Severity/Intensity Scale for Adverse Event
 - Description of Planned Arm
 - Planned Arm Code
 - Global Improvement
 - Domain Abbreviation (CM)
 - Category for Medication
 - Relation to Reference Period (CM)
 - Unit (CM)
 - CUE_EXPF_X
 - Domain Abbreviation (DA)
 - Drug Accountability Test Name
 - Drug Accountability Test Code
 - Reason for Discontinuation
 - Domain Abbreviation (DM)
 - Domain Abbreviation (DS)
 - Category for Disposition Event
 - Domain Abbreviation (EG)
 - Unit (EGRESU)
 - ECG Test Name**
 - ECG Test Code**

ECG Test Name [CL.EGTEST, C71152]

Permitted Value (Code)
Interpretation [C41255]
QTcB - Bazett's Correction Formula [C62112]
QTcF - Fridericia's Correction Formula [C62113]
Summary (Mean) PR Duration [C62086]
Summary (Mean) QRS Duration [C62087]
Summary (Mean) QT Duration [C62089]
Summary (Mean) Ventricular Rate [C62152]

ECG Test Code [CL.EGTESTCD, C71153]

Permitted Value (Code)	Display Value (Decode)
INTP [C41255]	Interpretation
PRMEAN [C62086]	Summary (Mean) PR Duration
QRS DUR [C62087]	Summary (Mean) QRS Duration
QTcB [C62112]	QTcB - Bazett's Correction Formula
QTcF [C62113]	QTcF - Fridericia's Correction Formula
QTMEAN [C62089]	Summary (Mean) QT Duration
VRMEAN [C62152]	Summary (Mean) Ventricular Rate

However, in the current define.xml v2.0 example the NCI codes were omitted for Questionnaire values and QSTEST / QSTESTCD Codelist

SDTM-IG 3.1.2

- Annotated Case Report Form
- Reviewers Guide
- Complex Algorithms
- ▶ Tabulation Datasets
- ▶ Value Level Metadata
- ▼ Controlled Terminology
 - ▼ Controlled Terms
 - Action Taken with Study Treatment
 - Domain Abbreviation (AE)
 - Relation to Reference Period (AE)
 - Causality
 - Severity/Intensity Scale for Adverse Event
 - Description of Planned Arm
 - Planned Arm Code
 - Global Improvement
 - Domain Abbreviation (CM)
 - Category for Medication
 - Relation to Reference Period (CM)

QS Test Codes [CL.QSTESTCD] { NCI Code(s) missing, multiple required for QSTEST and QSTESTCD }

Permitted Value (Code)	Display Value (Decode)
CGIGLOB { NCI Code ? }	Global Improvement
CSDD01 { NCI Code ? }	Anxiety
CSDD02 { NCI Code ? }	Sadness
CSDD03 ...	Lack of Reactivity to Pleasant Events
CSDD04 ...	Irritability
CSDD05 ...	Agitation
CSDD06 ...	Retardation
CSDD07 ...	Multiple Physical Complaints
CSDD08 ...	Loss of Interest
CSDD09 ...	Appetite Loss
CSDD10 ...	Weight Loss
CSDD11 ...	Lack of Energy

Thank You!

Markus Stoll

Senior Data Standards Manager

emailto:m@rkus-stoll.de