

Questionnaire CT in define v2.0 - update -

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)

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

Situation in define.xml v2.0

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

- As existing NCI Codes of used Codelist's and CodelistItem's are required according to define-specification document ([Section 5.3.10.2](#)), one will have an issue if more than one Questionnaire is used within a trial. Reason, there is no unique NCI reference code for QSTEST/QSTESTCD as is in SDTM CT e.g. as for LBTEST/LBTESTCD
- Question to ODM Team: How to include multiple QSTEST and QSTESTCD NCI Codelist Alias values (not CodelistItem) as required according to define specification document? Or is there an exception for QSTEST and QSTESTCD and will it not be required in case of multiple Questionnaires are used within a trial?
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 if no special check for QS CT exist (multiple Alias codes for QSTEST and QSTESTCD possible). Is this well known by the ODM Team and the validation tool provider? Are checks for QSTEST and QSTESTCD different to other CT's and is it possible to define multiple Alias values?

XML Code examples for Codelists in define v2.0

Codelist Alias Name used

```
<CodeList OID="CL.EGTEST" Name="ECG Test Name" DataType="text">
  <EnumeratedItem CodedValue="Interpretation">
    <Alias Name="C41255" Context="nci:ExtCodeID"/>
  </EnumeratedItem>
  <EnumeratedItem CodedValue="QTcB - Bazett's Correction Formula">
    <Alias Name="C62112" Context="nci:ExtCodeID"/>
  </EnumeratedItem>
  <EnumeratedItem CodedValue="QTcF - Fridericia's Correction Formula">
    <Alias Name="C62113" Context="nci:ExtCodeID"/>
  </EnumeratedItem>
  ...
  <Alias Name="C71152" Context="nci:ExtCodeID"/>
</CodeList>
```

Codelist Alias Name not used

```
<CodeList OID="CL.QSTESTCD" Name="QS Test Codes" DataType="text" SASFormatName="$QSTESTC">
  <CodeListItem CodedValue="CGIGLOB">
    <Decode>
      <TranslatedText xml:lang="en">Global Improvement</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="CSDD01">
    <Decode>
      <TranslatedText xml:lang="en">Anxiety</TranslatedText>
    </Decode>
  ...
</CodeList>
```

Define.xml v2.0 Example using ,Alias Name‘

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

Define.xml v2.0 Example **not** using ,Alias Name‘

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

CDISC CT update: Dec-18th-2015

The December 18, 2015 release brought changes to the SDTM data files -- notably, the standalone Questionnaires, Ratings, and Scales (QRS) Terminology has been deprecated and its content subsumed into the Study Data Tabulation Model (SDTM) Terminology publication file.

Result of Merge... **No Change!**

Issue of multiple C-Codes for Questionnaire CT persists as Questionnaire CT's are not kept under one NCI code for QSTEST / QSTESTCD, but still with a separate NCI code for each distinct Questionnaire.

Expected Impact - Low to none! Currently no impact expected at all as (so far) FDA might not even look into /check such details in define.xml v2.0 code.

But what about ODM QC programs? As not for all QSTEST and --TESTCD an NCI code exist I do not expect more than a „warning“ in case of a missing „Alias“.

Thank You

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Define-XML Specification (v2.0)

5.3.10.2. Alias Element

The Alias element provides a reference to the Domain description in the case where an ItemGroupDef represents a split domain or a reference to a C-Code when a CodeList, CodeListItem or EnumeratedItem corresponds to a CDISC Controlled Terminology.

Element Name: Alias

Element XPath(s): /ODM/Study/MetaDataVersion/ItemGroupDef/Alias
/ODM/Study/MetaDataVersion/CodeList/Alias
/ODM/Study/MetaDataVersion/CodeList/CodeListItem/Alias
/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/Alias

Element Textual Value: None

Usage Requirement: Conditional
Cardinality: One or more

- When used for regulatory submission, the Alias element is required for each ItemGroup that is part of a Domain that has been split into different datasets.
- When used for regulatory submission of SDTM, ADaM or SEND metadata, **the Alias element is required for each CodeList that represents a CDISC Controlled Terminology** and for each EnumeratedItem of CodeListItem element that represents a CDISC defined term in a CDISC Controlled Terminology.

Attributes: Context, Name

Child Elements : None



Frage: Timing Variable Order in SE

Martina.Krueger@Boehringer-Ingelheim.com (03.03.2016)

Defined order in SE (SDTM IG 3.2):

...
SESTDTC
SEENDTC
TAETORD
EPOCH
...

According to CDER: add –STDY / –ENDY

> SDTM 1.4 schreibt dafür die Order nach den –DTC Variablen vor:

...
SESTDTC
SEENDTC
SESTDY
SEENDY
TAETORD
EPOCH
...

Order nach SDTM Model 1.4 führt allerdings zum Pinnacle21 Validator Finding:

SD1079	Variable is in wrong order within domain	Order of variables should be as specified by CDISC standard
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Frage: Timing Variable Order in SE

Martina.Krueger@Boehringer-Ingelheim.com (03.03.2016)

Tatsache ist, dass die Definition in SE gegenüber der anderen Domänen für EPOCH und TAETORD anders ist!

SDTM 1.4 Timing Variables for Observation Classes	SDTM IG 3.2 SE Domain	SE Domain with additional timing =>Error	SE Domain with additional timing No Error!
TAETORD			
EPOCH			
xxSTDTC	SESTDTC	SESTDTC	SESTDTC
xxENDTC	SEENDTC	SEENDTC	SEENDTC
			TAETORD
			EPOCH
xxSTDY		SESTDY	SESTDY
xxENDY		SEENDY	SEENDY
	TAETORD	TAETORD	
	EPOCH	EPOCH	

Frage: Wie geht die Community mit diesem Finding um?