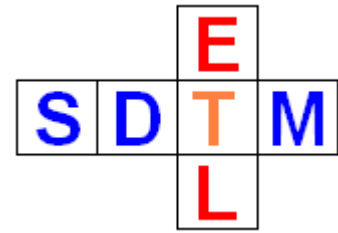


## SDTM-ETL 3.1 User Manual and Tutorial

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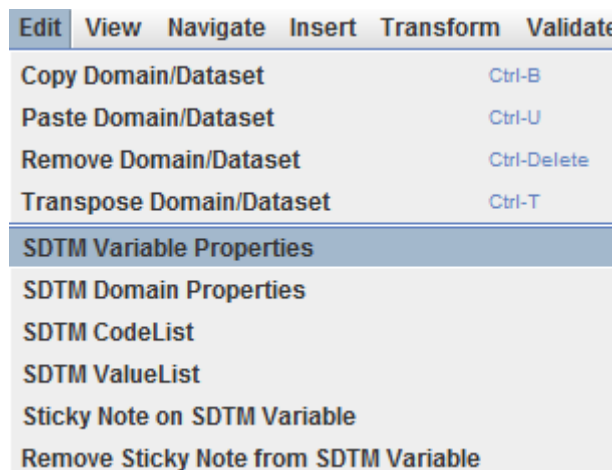


### **Editing the define.xml ItemDef properties (SDTM Variable properties)**

In the define.xml, an SDTM Variable is defined by its “ItemRef – ItemDef” pair.

So, if we want to e.g. change the maximal (string) length of an SDTM variable, we need to edit the “ItemDef” properties of that SDTM variable in the define.xml structure. In SDTM-ETL, this is however mostly hidden for the normal user.

In order to change the properties of an SDTM variable, select a cell representing an SDTM variable (in this example case, select QS.QSTEST) in the SDTM table and select “Edit -> SDTM Variable Properties”.



A dialog is shown, allowing to edit some of the properties of the corresponding define.xml ItemDef: The default length for QS.QSTEST was 40, but we set it to 20, because we know that its value will never be larger than 20:

**Edit Properties for SDTM Variable QS.QSTEST**

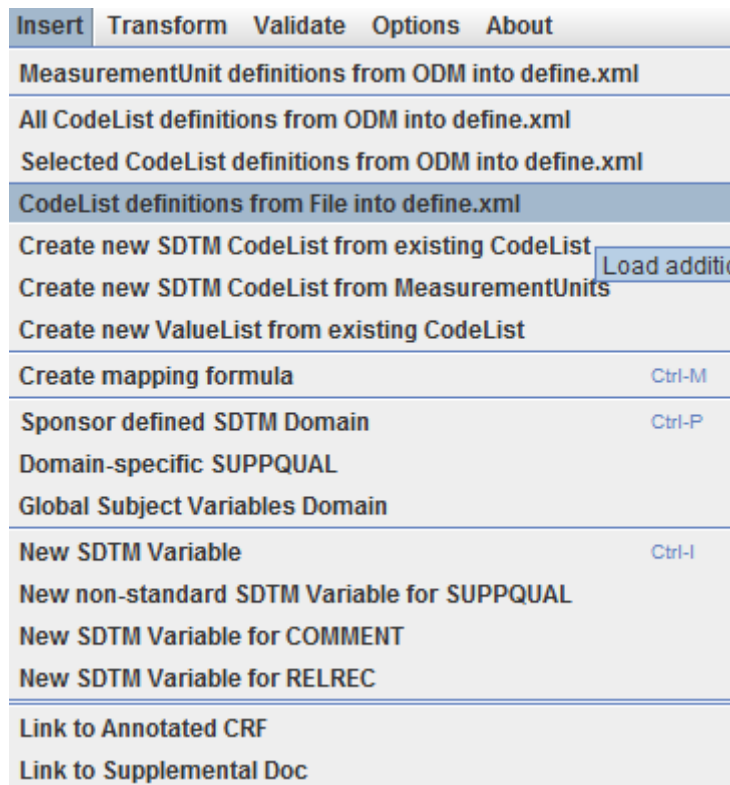
**OID:** QS.QSTEST  
**Name:** QSTEST  
**Data type:** text  
**Current Length:** 40  
 **New Length:** 40  
**Current Significant Digits:**  
 **New Significant Digits:** -1  
**Current Role:**  
 **New Role:**  
**Current Role CodeList:**  
 **New Role CodeList:** CL.VSTESTCD - Vital Signs Test Code(text)  
**Current Origin:** NONE DEFINED YET  
 **New Origin:** Edit  
**Comment:**  
**Current CodeList:** NO CODELIST ASSIGNED  
 **New CodeList:** CL.VSTESTCD - Vital Signs Test Code(text)  
**Description:** Question Name  
**current def:DisplayFormat:**  
 **New def:DisplayFormat:**  
 **New def:ComputationMethodOID:** COMP.QS.QSTEST  
**def:ComputationMethod description:**  
**current ValueList OID:** NO VALUelist ASSIGNED  
 **New ValueList OID:** NO VALUelist  
 OK Cancel

We tick the “New Length” checkbox. An input field becomes available, where we type “20”:

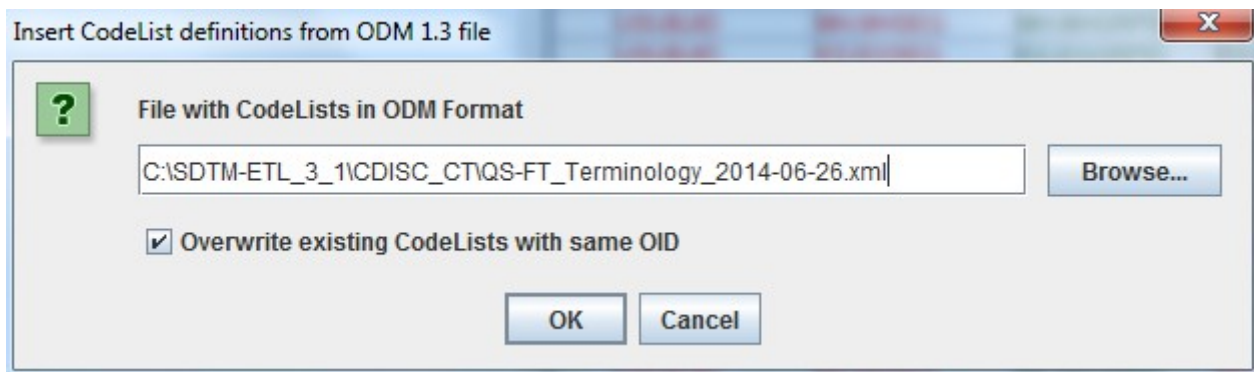
**OID:** QS.QSTEST  
**Name:** QSTEST  
**Data type:** text  
**Current Length:** 40  
 **New Length:** 20

As one sees, one can also change the associated codelist (if any), and some other “ItemDef” properties in the define.xml structure.

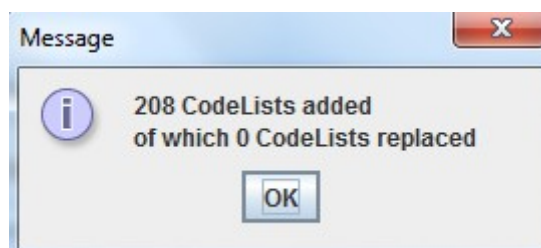
For example, if we know that QSTEST follows the latest CDISC controlled terminology, we first need to insert the QS-codelists. In order to do so, first click „OK“ and then use the menu „Insert – CodeList definitions from File into define.xml,



and e.g. choose the file „QS-FT\_Terminology\_2014-06-26.xml“ (which you can find in the directory „CDISC-CT“):



A confirmation message is displayed:



If you know edit the properties for „QSTEST“ again, you can associate the corresponding codelist, e.g.:

<b>Current CodeList</b>	NO CODELIST ASSIGNED
<input checked="" type="checkbox"/> New CodeList:	CL.VSTESTCD - Vital Signs Test Code(text)
<b>Description:</b>	CL.C112435.AQ20 TESTCD - QS-Airway Questionnaire 20 Test Code(text)
<b>current def:DisplayFormat:</b>	CL.C112434.AQ20 TEST - QS-Airway Questionnaire 20 Test Name(text)
<input type="checkbox"/> New def:DisplayFormat:	CL.C100132.ADAS-Cog CDISC Version TESTCD - QS-Alzheimer's Disease Assessment Scale - Cognitive CI
<input type="checkbox"/> New def:ComputationMethodOID:	CL.C100131.ADAS-Cog CDISC Version TEST - QS-Alzheimer's Disease Assessment Scale - Cognitive CDIS
	CL.C106651.ADCS-ADL MCI TESTCD - QS-Alzheimer's Disease Cooperative Study-Activities of Daily Living

Remind that this is just an example, you might need a completely different codelist in your case.

Click OK to confirm your edits.

If you already had a codelist for QSTEST test names in your ODM, you can of course also import that one in the underlying define.xml, e.g. using the menu „Insert – Selected CodeList definitions from ODM into define.xml“.

Other properties that you can add or change are the data type, length and significant digits (when appropriate, depending on the data type), role and role codelist. One can also add a comment, a display format and/or a reference to a computation method (when using define.xml this is the „ImputationMethod“). It is however strongly discouraged to change the latter, as it contains the mapping script!

One can also associate a „ValueList“, which usually only makes sense when the variable is an --ORRES, --ORRESU, --STRES, --STRESU or a --QVAL variable (see the [define.xml 2.0 specification](#) section 4.4).

Generation of ValueLists is explained in a different tutorial.