SDTM-ETL 3.0 User Manual and Tutorial

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Working with „Medical Devices“ domains

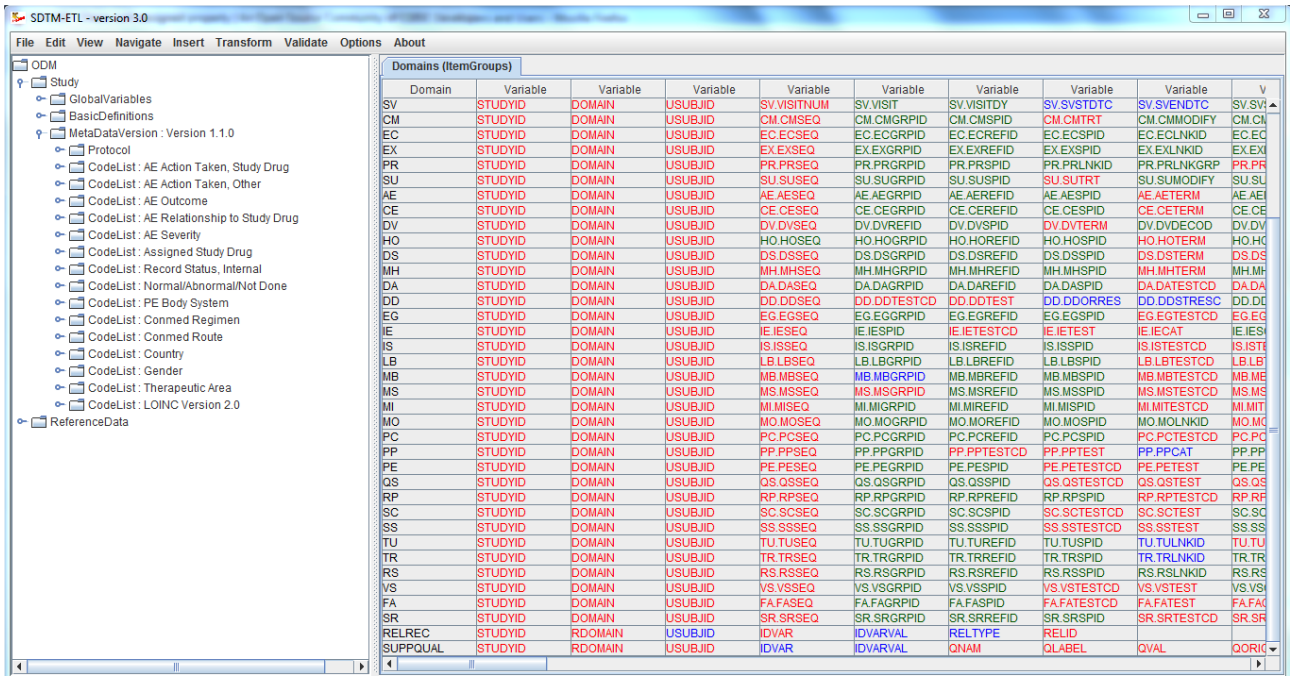
The Implementation Guide for „Medical Devices“ (further designated as SDTM-IG-MD) has recently become „final“ (v.1.0). In principal it is to be used in combination with SDTM 1.4 (SDTM-IG 3.2), but it can also be used in combination with SDTM 1.3 (SDTM-IG 3.1.3).

The following domains have been published:

- DI: Device Indentifiers
- DU: Devices in Use
- DX: Devices Exposure
- DE: Devices Events
- DT: Device Tracking and Disposition
- DR: Device-Subject Relationships
- DO: Device Properrties

When loading the templates for either SDTM 1.3 or 1.4, these domains will not be loaded automatically, but you can easily add them.

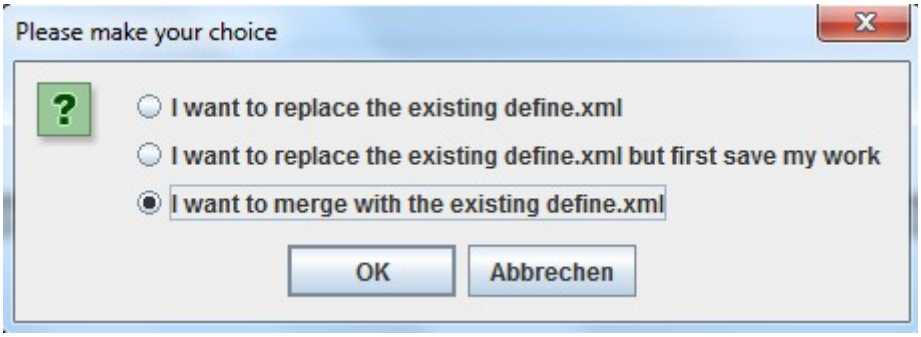
If you have loaded the templates for SDTM 1.4, you will see the following:



As SDTM 1.4 has many more domains than 1.3, your screen may be completely filled, but you can easily only display the domains that are currently of interest to you using the menu „View – View/Hide Domains“.

We now also want to load the „Medical Devices“ domains.

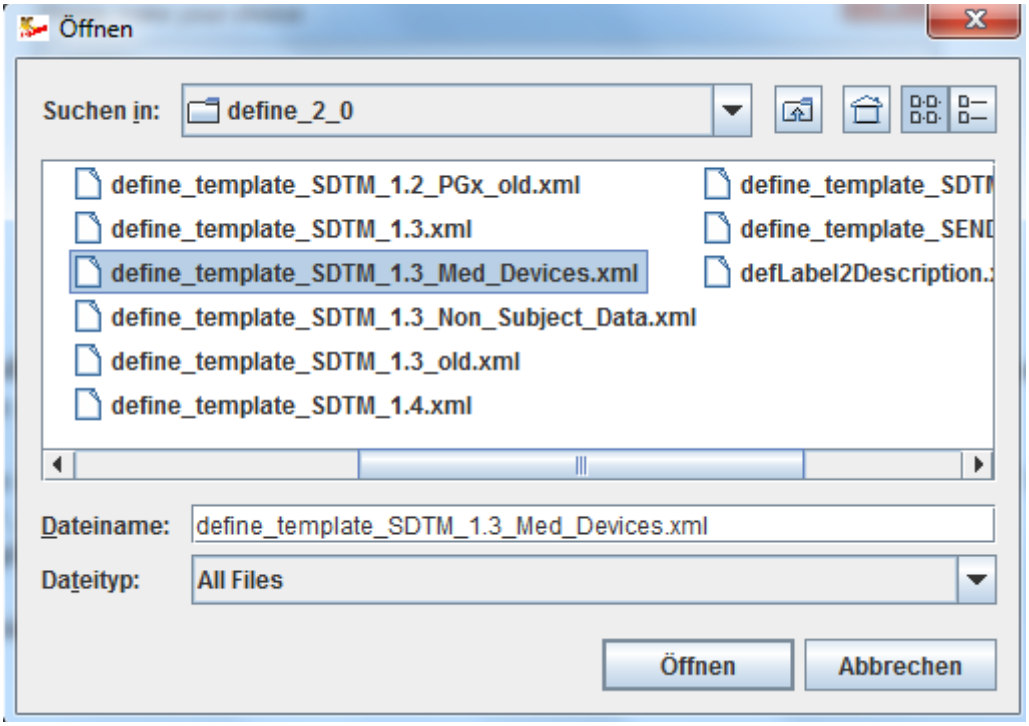
In order to do so, use the menu „File – Load Study define.xml“ or just use CTRL-D. The following dialog is displayed:



Select the radiobutton „I want to merge with the existing define.xml“, and click „OK“. You are then prompted for a file.

The template define.xml file for „Medical Devices“ is located in the directory „define_2_0“ and in the directory „define_1_0“ in your distribution. The file name is „define_template_SDTM_1.3_Med_Devices.xml“.

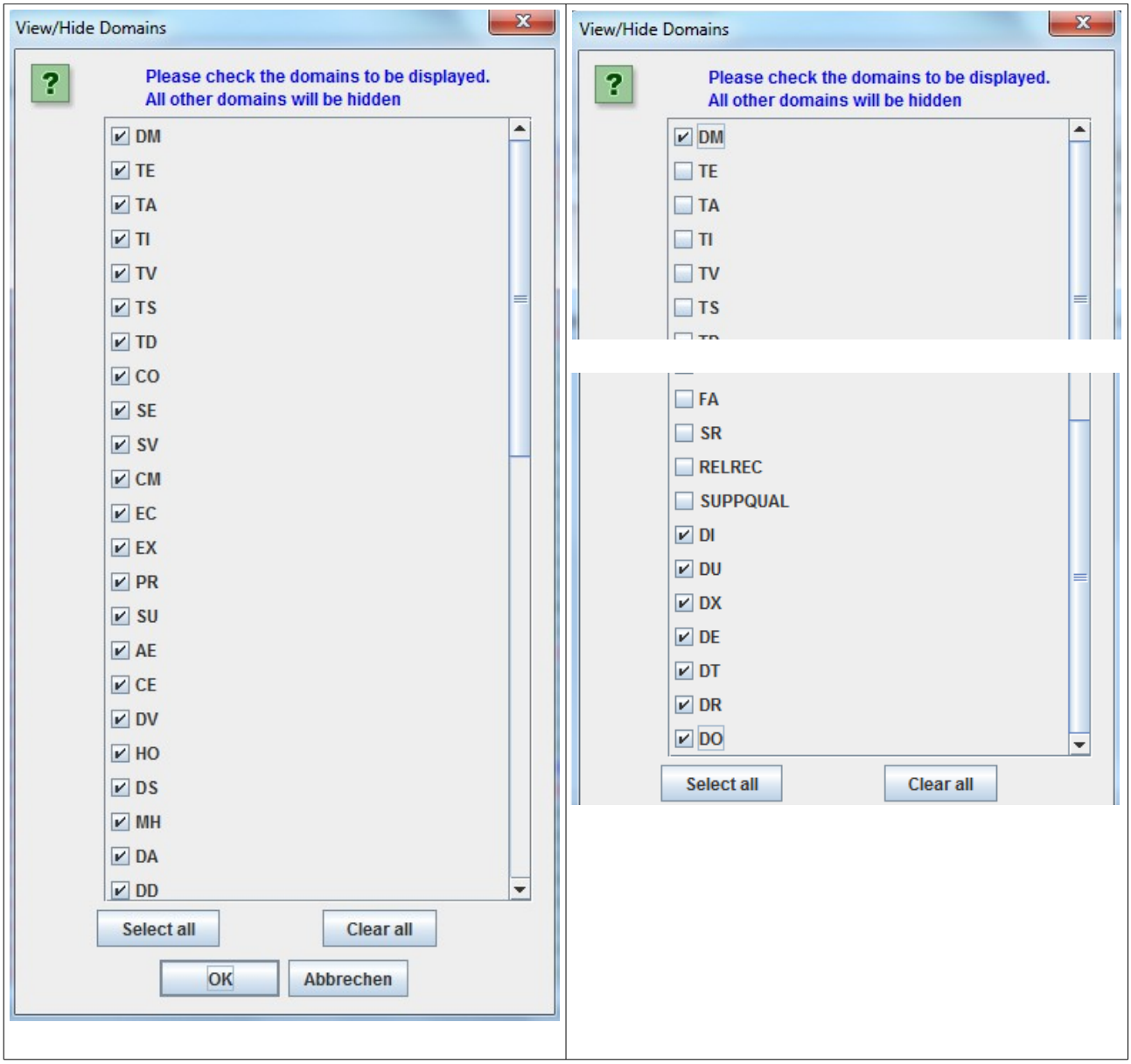
As we are using define.xml 2.0, we need to take the one from the „define_2_0“ directory:



After clicking OK, the template is loaded and merged with all the already loaded template domains:

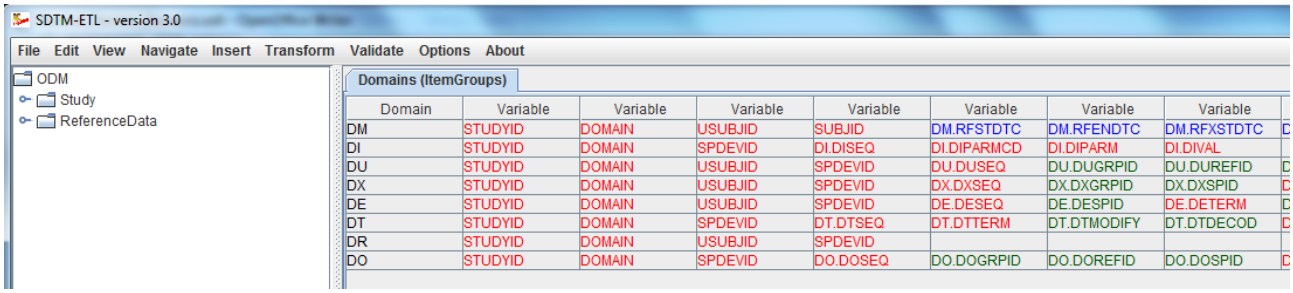
TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKID	TU.TUTESTC
TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TRREFID	TR.TRSPID	TR.TRLNKID	TR.TRLNKGR
RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSGRPID	RS.RSREFID	RS.RSSPID	RS.RSLNKID	RS.RSLNKGR
VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VSCAT
FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST	FA.FAOBJ
SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTESTCD	SR.SRTEST
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID		
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
DI	STUDYID	DOMAIN	SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM	DI.DIVAL		
DU	STUDYID	DOMAIN	USUBJID	SPDEVID	DU.DUSEQ	DU.DUGRPID	DU.DUREFID	DU.DUSPID	DU.DUTESTC
DX	STUDYID	DOMAIN	USUBJID	SPDEVID	DX.DXSEQ	DX.DXGRPID	DX.DXSPID	DX.DXTRT	DX.DXCAT
DE	STUDYID	DOMAIN	USUBJID	SPDEVID	DE.DESEQ	DE.DESPID	DE.DETERM	DE.DEMODIFY	DE.DEDECOD
DT	STUDYID	DOMAIN	SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY	DT.DTDECOD	DT.DTPARTY	DT.DTPRTYID
DR	STUDYID	DOMAIN	USUBJID	SPDEVID					
DO	STUDYID	DOMAIN	SPDEVID	DO.DOSEQ	DO.DOGRPID	DO.DOREFID	DO.DOSPID	DO.DOTESTCD	DO.DOTEST

The screen is even more overloaded with information (over 50 domains!) but you can easily make life easier by only showing the domains that are currently of interest to you (and hiding all others) by using the menu „View – View/Hide Domains“, leading to e.g.:



Where we only kept DM and the medical devices domains and hide all others.

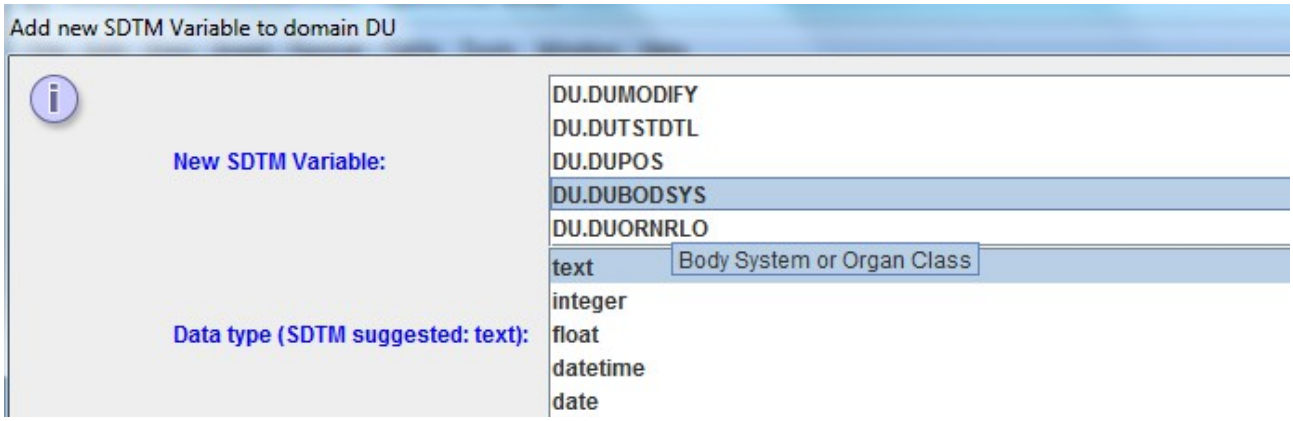
This leads to:



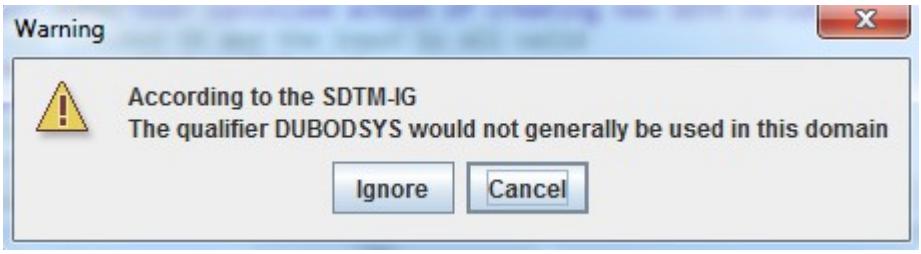
Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable
DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC	DM.RFXSTDTC
DI	STUDYID	DOMAIN	SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM	DI.DIVAL
DU	STUDYID	DOMAIN	USUBJID	SPDEVID	DU.DUSEQ	DU.DUGRPID	DU.DUREFID
DX	STUDYID	DOMAIN	USUBJID	SPDEVID	DX.DXSEQ	DX.DXGRPID	DX.DXSPID
DE	STUDYID	DOMAIN	USUBJID	SPDEVID	DE.DESEQ	DE.DESPID	DE.DETERM
DT	STUDYID	DOMAIN	SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY	DT.DTDECOD
DR	STUDYID	DOMAIN	USUBJID	SPDEVID			
DO	STUDYID	DOMAIN	SPDEVID	DO.DOSEQ	DO.DOGRPID	DO.DOREFID	DO.DOSPID

As usual, we now also can get information about a single variable by selecting its cell and using the menu „View – SDTM CDISC Notes“ (or using CTRL-H).
For example for „SPDEVID“ in „DU“:

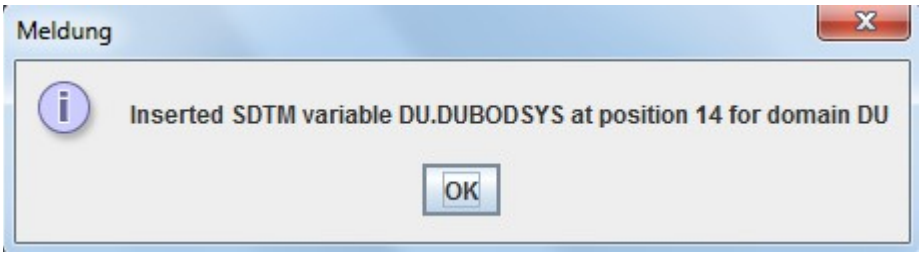
As for any other domain, we can add additional variables, even though some of them are „discouraged“ (e.g. the SDTM-IG stating „The following Qualifiers would not generally be used in ...“). For example, if we would like to add „BODSYS“ to the DU domain, using the menu „Insert – New SDTM Variable“:



we will get the following warning:



You can now decide to cancel the insert completely, or to ignore the warning and add the new variable anyway. If we do the latter, we obtain:



and we find:

Domains (ItemGroups)

able	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Va
ID	DU.DUTESTCD	DU.DUTEST	DU.DUCAT	DU.DUSCAT	DU.DUBODSYS	DU.DUORRES	DU.DUORRESU	DU.DUS
T	DX.DXCAT	DX.DXSCAT	DX.DXDOSE	DX.DXDOSTXT	DX.DXDOSU	DX.DXDOSFRQ	DX.DXDOSTOT	DX.DXD
DIFY	DE.DEDECOD	DE.DECAT	DE.DESCAT	DE.DEPRESP	DE.DEOCCUR	DE.DESTAT	DE.DEREASND	DE.DES
RTY	DT.DTPRTYID	DT.DTCAT	DT.DTSCAT	DT.DTDTC	DT.DTSTDTC			
STCD	DO.DOTEST	DO.DOCAT	DO.DOSCAT	DO.DOORRES	DO.DOORRESU			

We can now starting mapping between our collected data in ODM format and any of the „Medical Devices“ domains.