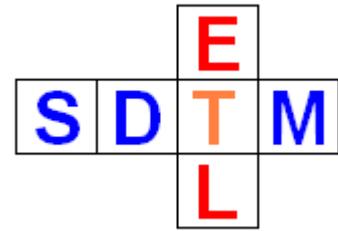


SDTM-ETL 3.0 User Manual and Tutorial

Author: Jozef Aerts, XML4Pharma

Last update: 2014-03-29



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 Identifiers
- DU: Devices in Use
- DX: Devices Exposure
- DE: Devices Events
- DT: Device Tracking and Disposition
- DR: Device-Subject Relationships
- DO: Device Properties

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.

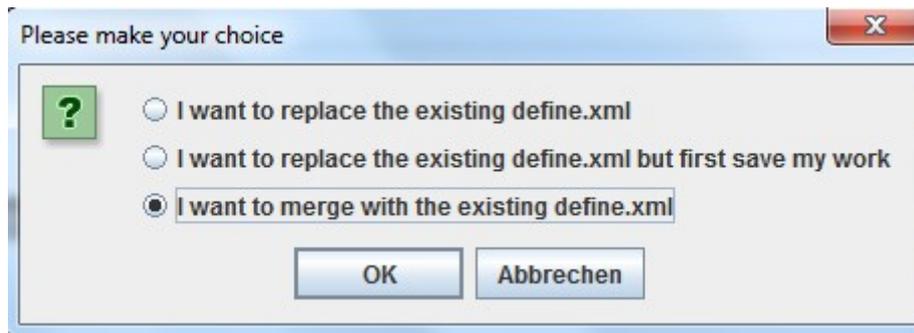
If you have loaded the templates for SDTM 1.4, you will see the following:

Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable
SV	STUDYID	DOMAIN	USUBJID	SV.VISITNUM	SV.VISIT	SV.VISITDY	SV.SVSTOTC	SV.SVENDTC	SV.SV	
CM	STUDYID	DOMAIN	USUBJID	CM.CMSEQ	CM.CMGRPID	CM.CMSPID	CM.CMTRT	CM.CMMODIFY	CM.CM	
EC	STUDYID	DOMAIN	USUBJID	EC.ECSEQ	EC.ECGRPID	EC.ECREPID	EC.ECSPID	EC.ECLNKID	EC.EC	
EX	STUDYID	DOMAIN	USUBJID	EX.EXSEQ	EX.EXGRPID	EX.EXREFID	EX.EXSPID	EX.EXLNKID	EX.EX	
PR	STUDYID	DOMAIN	USUBJID	PR.PRSEQ	PR.PRGRPID	PR.PRSPID	PR.PRLNKID	PR.PRLNKGRP	PR.PR	
SU	STUDYID	DOMAIN	USUBJID	SU.SUSEQ	SU.SUGRPID	SU.SUSPID	SU.SUTRT	SU.SUMODIFY	SU.SU	
AE	STUDYID	DOMAIN	USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID	AE.AESPID	AE.AETERM	AE.AE	
CE	STUDYID	DOMAIN	USUBJID	CE.CESEQ	CE.CEGRPID	CE.CEREFID	CE.CESPID	CE.CETERM	CE.CE	
DV	STUDYID	DOMAIN	USUBJID	DV.DVSEQ	DV.DVREFID	DV.DVSPID	DV.DVTERM	DV.DVDECOD	DV.DV	
HO	STUDYID	DOMAIN	USUBJID	HO.HOSEQ	HO.HOGRPID	HO.HOREPID	HO.HOSPID	HO.HOTERM	HO.HO	
DS	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSPID	DS.DSTERM	DS.DS	
MH	STUDYID	DOMAIN	USUBJID	MH.MHSEQ	MH.MHGRPID	MH.MHREFID	MH.MHSPID	MH.MHTERM	MH.MH	
DA	STUDYID	DOMAIN	USUBJID	DA.DASEQ	DA.DAGRPID	DA.DAREPID	DA.DASPID	DA.DATESTCD	DA.DA	
DD	STUDYID	DOMAIN	USUBJID	DD.DDSEQ	DD.DDTESTCD	DD.DDTEST	DD.DDORRES	DD.DDSTRESC	DD.DD	
EG	STUDYID	DOMAIN	USUBJID	EG.EGSEQ	EG.EGGRPID	EG.EGREPID	EG.EGSPID	EG.EGSTESTCD	EG.EG	
IE	STUDYID	DOMAIN	USUBJID	IE.IESEQ	IE.IESPID	IE.IESTESTCD	IE.IESTEST	IE.IECAT	IE.IE	
IS	STUDYID	DOMAIN	USUBJID	IS.ISSEQ	IS.ISGRPID	IS.ISREFID	IS.ISSPID	IS.ISTESTCD	IS.IS	
LB	STUDYID	DOMAIN	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTESTCD	LB.LB	
MB	STUDYID	DOMAIN	USUBJID	MB.MBSEQ	MB.MBGRPID	MB.MBREFID	MB.MBSPID	MB.MBTESTCD	MB.MB	
MS	STUDYID	DOMAIN	USUBJID	MS.MSSEQ	MS.MSGRPID	MS.MSREFID	MS.MSPID	MS.MSTESTCD	MS.MS	
MI	STUDYID	DOMAIN	USUBJID	MI.MISEQ	MI.MIGRPID	MI.MIREPID	MI.MISPID	MI.MITESTCD	MI.MI	
MO	STUDYID	DOMAIN	USUBJID	MO.MOSEQ	MO.MOGRPID	MO.MOREPID	MO.MOSPID	MO.MOLNKID	MO.MO	
PC	STUDYID	DOMAIN	USUBJID	PC.PCSEQ	PC.PCGRPID	PC.PCREFID	PC.PCSPID	PC.PCTESTCD	PC.PC	
PP	STUDYID	DOMAIN	USUBJID	PP.PPSEQ	PP.PPGRPID	PP.PPTESTCD	PP.PPTEST	PP.PPCAT	PP.PP	
PE	STUDYID	DOMAIN	USUBJID	PE.PESEQ	PE.PEGRPID	PE.PESPID	PE.PETESTCD	PE.PETEST	PE.PE	
QS	STUDYID	DOMAIN	USUBJID	QS.QSSEQ	QS.QSGRPID	QS.QSPID	QS.QSTESTCD	QS.QSTEST	QS.QS	
RP	STUDYID	DOMAIN	USUBJID	RP.RPSEQ	RP.RPGRPID	RP.RPREPID	RP.RPSPID	RP.RPTESTCD	RP.RP	
SC	STUDYID	DOMAIN	USUBJID	SC.SCSEQ	SC.SCGRPID	SC.SCSPID	SC.SCTESTCD	SC.SCTEST	SC.SC	
SS	STUDYID	DOMAIN	USUBJID	SS.SSSEQ	SS.SSGRPID	SS.SSPID	SS.SSTESTCD	SS.SSTEST	SS.SS	
TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREPID	TU.TUSPID	TU.TULNKID	TU.TU	
TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TREFID	TR.TRSPID	TR.TRLNKID	TR.TR	
RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSGRPID	RS.RSREFID	RS.RSPID	RS.RSLNKID	RS.RS	
VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSREFID	VS.VSTESTCD	VS.VSTEST	VS.VS	
FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST	FA.FA	
SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTESTCD	SR.SR	
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID			
SUPPEQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	

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.

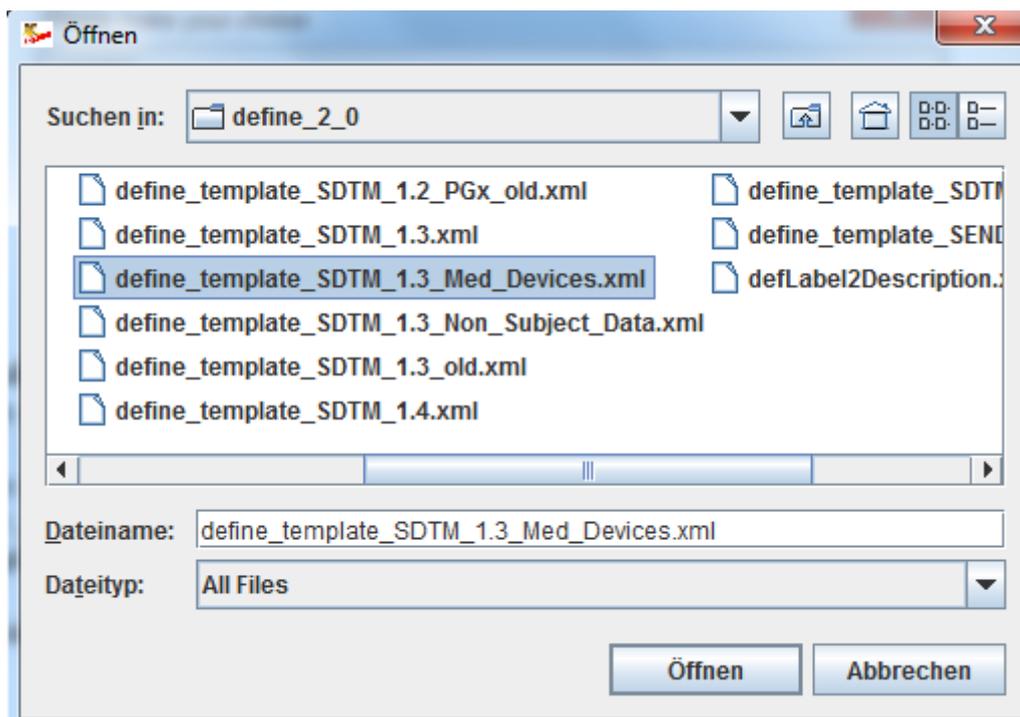
In order to do so, use the menu „File – Load Study define.xml“ or just use CTRL-D. The following dialog is displayed:



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“.

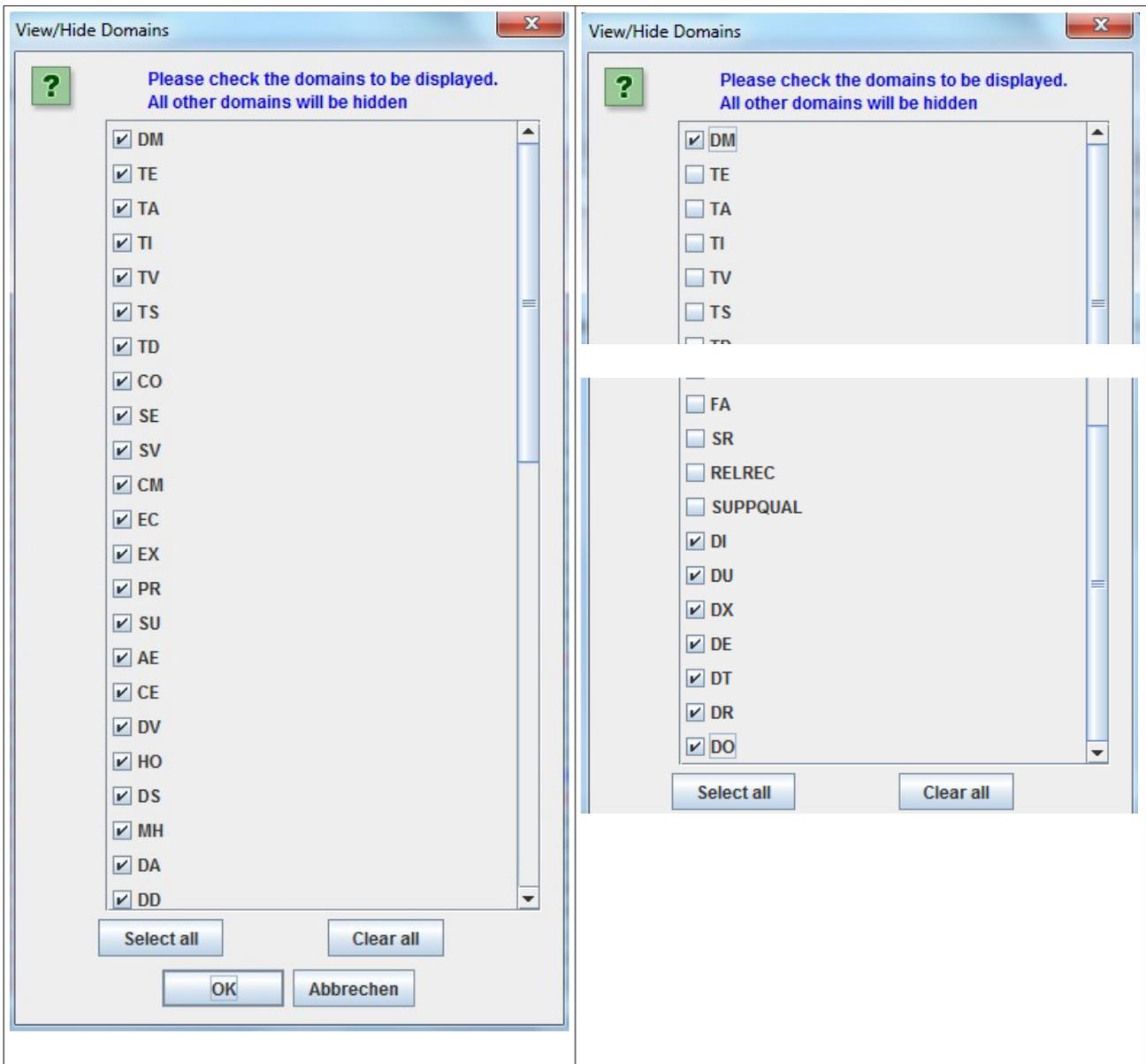
As we are using define.xml 2.0, we need to take the one from the „define_2_0“ directory:



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

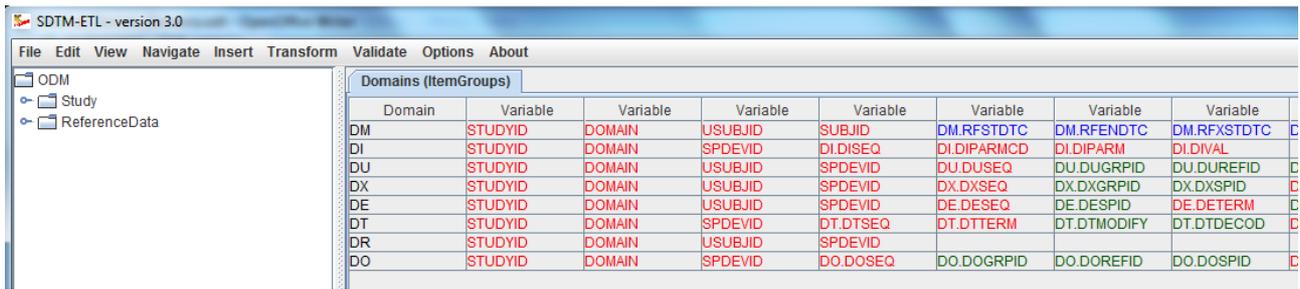
TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKID	TU.TUTESTCD
TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TRREFID	TR.TRSPID	TR.TRLNKID	TR.TRLNKGR
RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSRPID	RS.RSREFID	RS.RSSPID	RS.RSLNKID	RS.RSLNKGR
VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSREFID	VS.VSPID	VS.VSTESTCD	VS.VSTEST
FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FAREFID	FA.FASPID	FA.FATESTCD	FA.FATEST
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	DU.DUSEQ	DU.DUGRPID	DU.DUREFID	DU.DUSPID	DU.DUTESTCD	DU.DUTEST
DX	STUDYID	DOMAIN	USUBJID	DX.DXSEQ	DX.DXGRPID	DX.DXSPID	DX.DXTRT	DX.DXCAT	
DE	STUDYID	DOMAIN	USUBJID	DE.DESEQ	DE.DESPID	DE.DETERM	DE.DEMODIFY	DE.DEDECOD	DE.DEDECOD
DT	STUDYID	DOMAIN	SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY	DT.DTDECOD	DT.DTPARTY	DT.DTPRTYID
DR	STUDYID	DOMAIN	USUBJID	DR.DRSEQ	DR.DRGRPID	DR.DRREFID	DR.DRSPID	DR.DRTESTCD	DR.DRTEST
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.

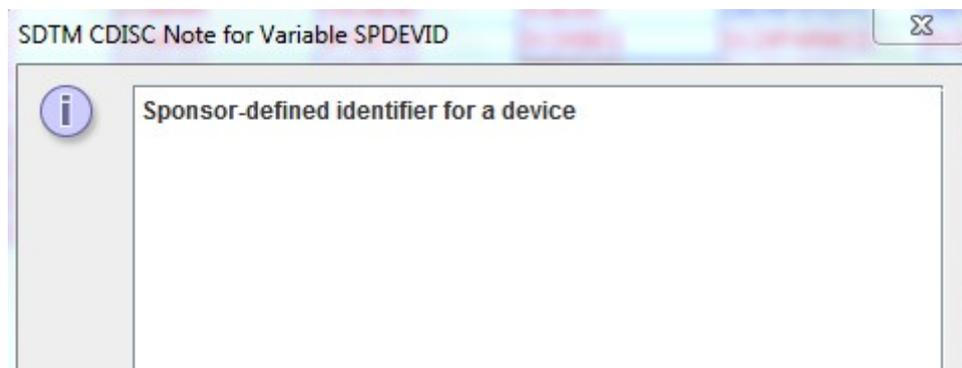
This leads to:



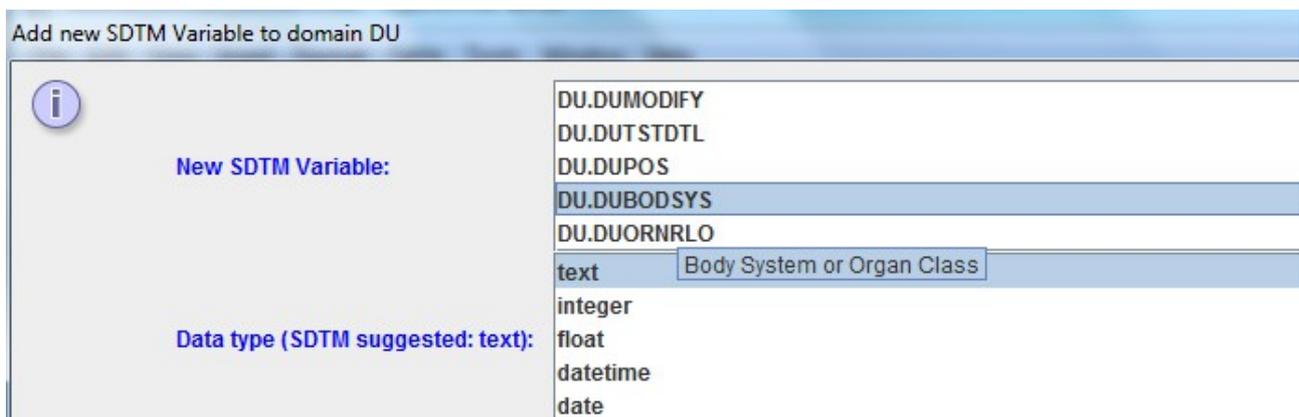
Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable
DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC	DM.RFXSTDTC
DI	STUDYID	DOMAIN	SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM	DI.DIVAL
DU	STUDYID	DOMAIN	USUBJID	SPDEVID	DU.DUSEQ	DU.DUGRPID	DU.DUREFID
DX	STUDYID	DOMAIN	USUBJID	SPDEVID	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).

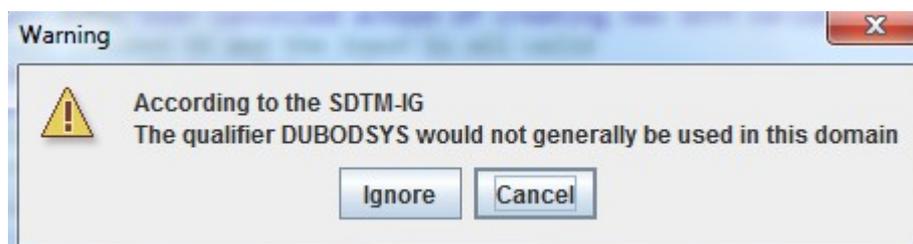
For example for „SPDEVID“ in „DU“:



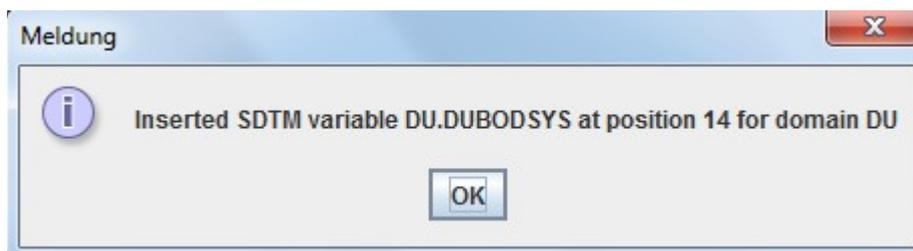
As for any other domain, we can add additional variables, even though some of them are „discouraged“ (e.g. the SDTM-IG stating „The following Qualifiers would not generally be used in ...“). For example, if we would like to add „BODSYS“ to the DU domain, using the menu „Insert – New SDTM Variable“:



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)								
Table	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable
ID	DU.DUTESTCD	DU.DUTEST	DU.DUCAT	DU.DUSCAT	DU.DUBODSYS	DU.DUORRES	DU.DUORRESU	DU.DUS
F	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.