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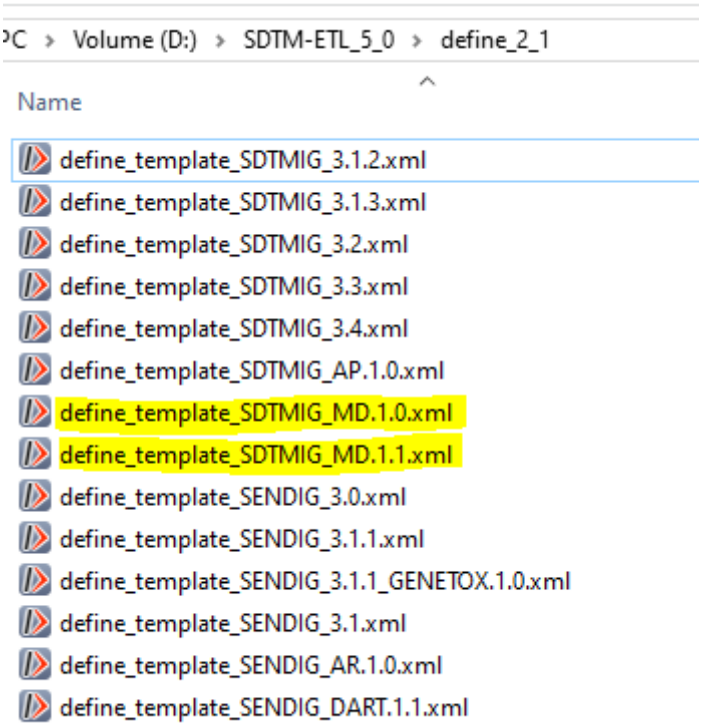
Working with "Medical Devices" domains

Loading Medical Devices templates

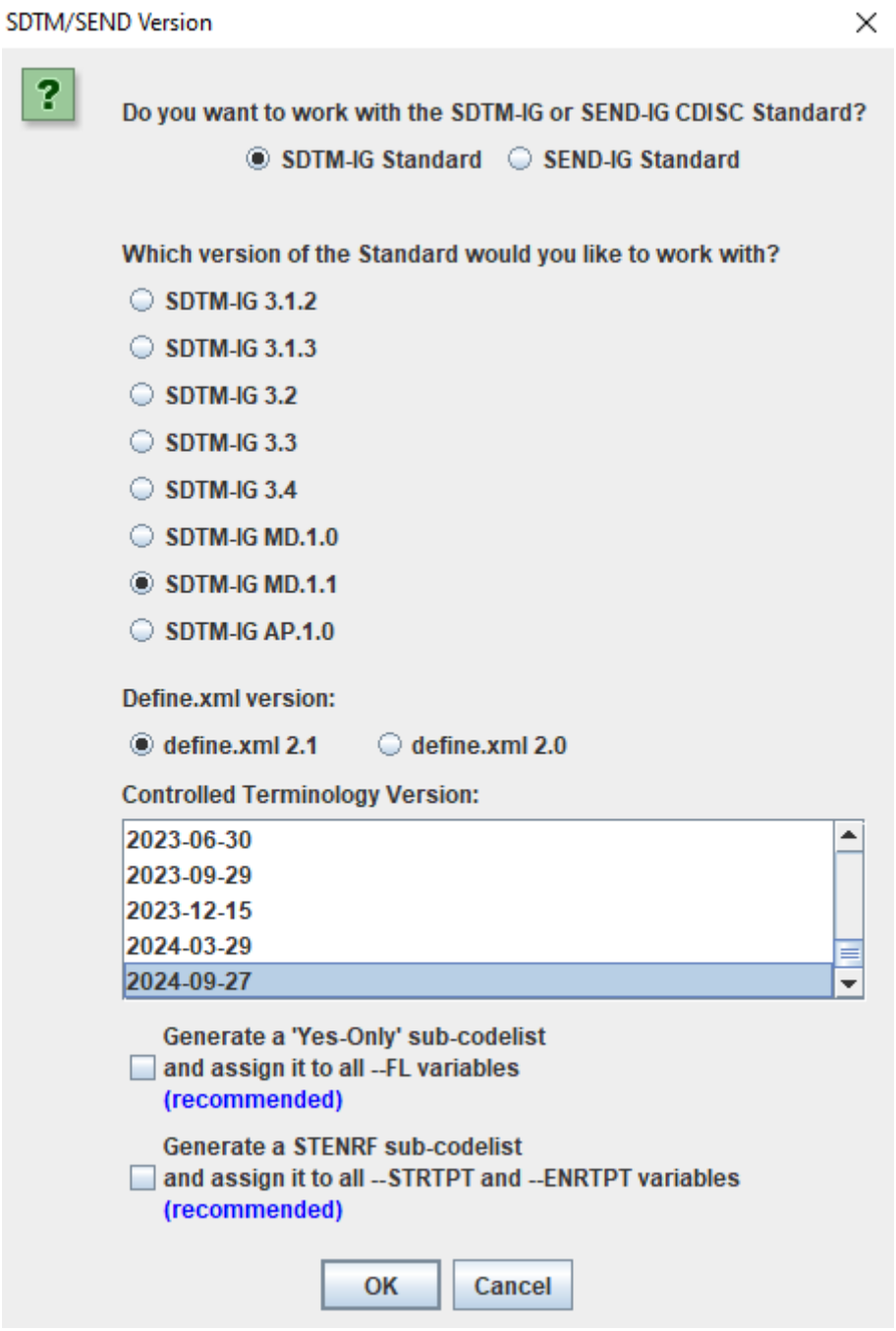
The CDISC "Medical Devices" SDTM domains are domains that can be used "on top" of the usual domains starting from SDTMIG-v.3.3. They can of course also be used for IG version 3.4.

The template files for these domains can be found in the directories "define_2_0" (for use with the Define-XML 2.0 standard) and "define_2_1" (for 2.1). For example, for use with Define-XML 2.1:

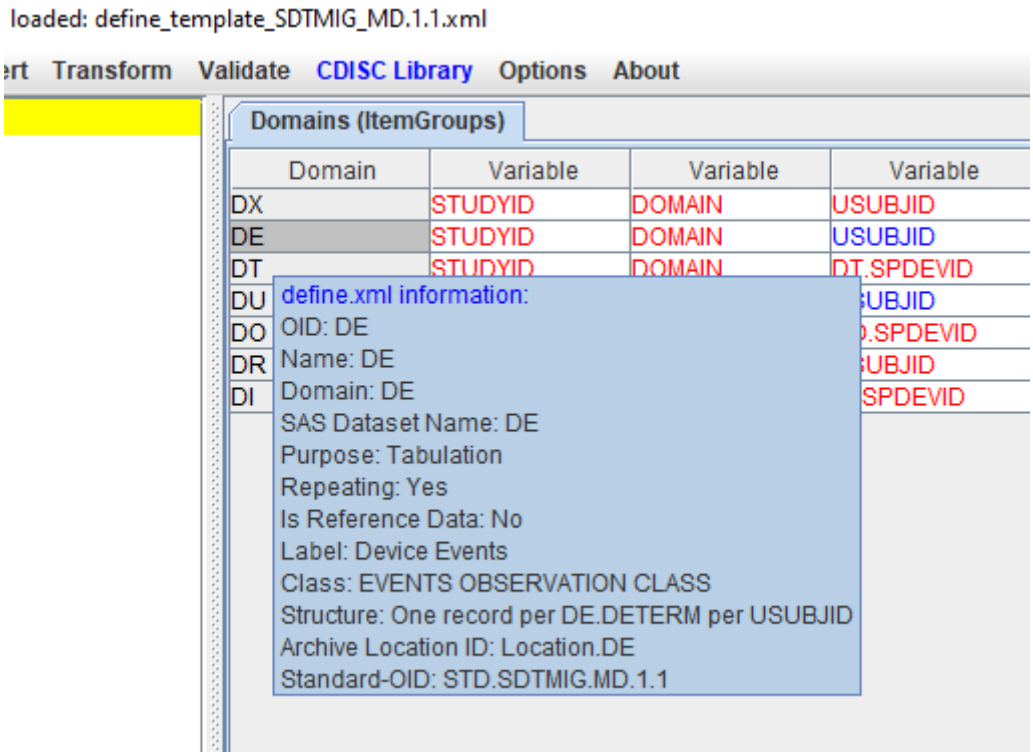


As one sees, there are templates available for both versions 1.0 as 1.1 of the "Medical Devices" standard. Version 1.1 is however recommended.

When, after having loaded an ODM file with metadata, one uses menu "File - Create define.xml" (Ctrl-N), one can already select "Medical Devices" from one of the templates. For example for define.xml 2.1 (recommended):

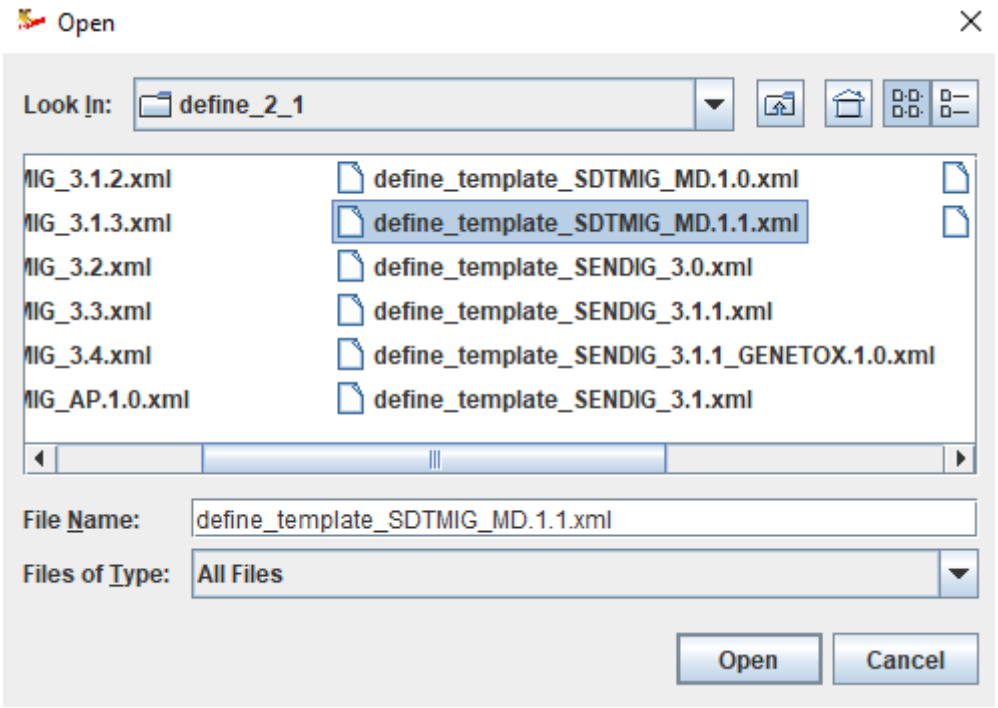


After selection (including a version of the Controlled Terminology) and clicking "OK", the template loads, leading to:

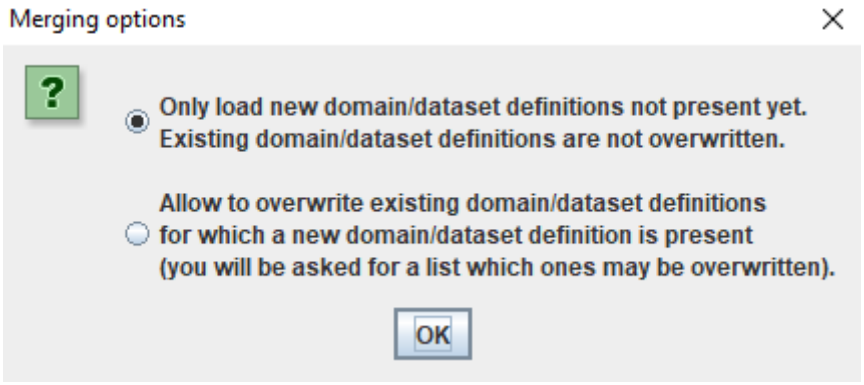


with only the MD-specific domains being loaded.

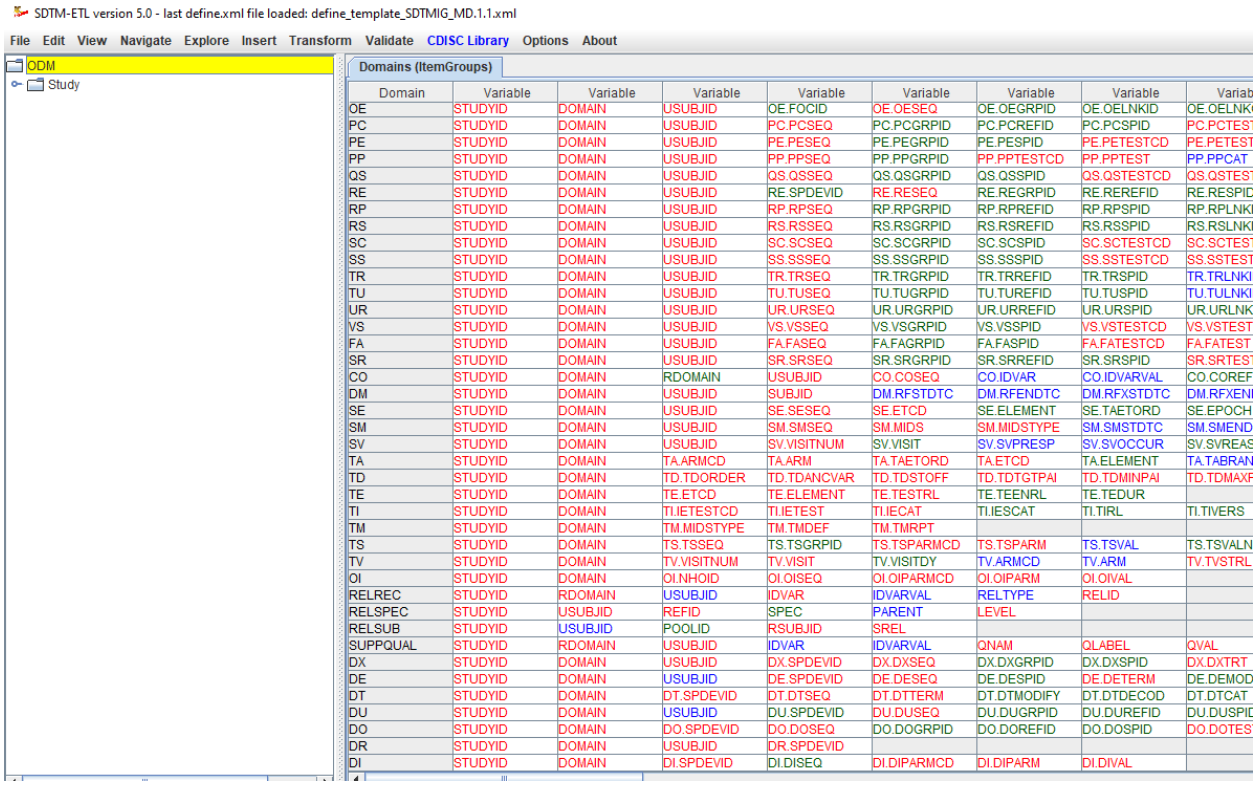
Often, one will want to have the "regular" domains being loaded used first, and then additionally add the MD-domains. In such a case, first load the template for the "regular" SDTMIG (e.g. version 3.3). and then use "File - Load template define.xml", then navigate to the SDTM-ETL define_2_1 directory, and then select the template file of choice, e.g.:



leading to the dialog:



Though there is no overlap in this case, selecting "Only new domain/dataset definitions" will be the fastest. This e.g. leads to:



Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variab
OE	STUDYID	DOMAIN	USUBJID	OE.FOCID	OE.OESEQ	OE.OEGRPID	OE.OELNKID	OE.OELNK
PC	STUDYID	DOMAIN	USUBJID	PC.PCSEQ	PC.PCGRPID	PC.PCREFID	PC.PCSPID	PC.PCTES
PE	STUDYID	DOMAIN	USUBJID	PE.PESEQ	PE.PEGRPID	PE.PESPID	PE.PETESTCD	PE.PETEST
PP	STUDYID	DOMAIN	USUBJID	PP.PPSEQ	PP.PPGRPID	PP.PPTESTCD	PP.PPTEST	PP.PPCAT
QS	STUDYID	DOMAIN	USUBJID	QS.QSSEQ	QS.QSGRPID	QS.QSSPID	QS.QSTESTCD	QS.QSTES
RE	STUDYID	DOMAIN	USUBJID	RE.SPDEVID	RE.RESEQ	RE.REGRPID	RE.REREFID	RE.RESPID
RP	STUDYID	DOMAIN	USUBJID	RP.RPSEQ	RP.RPGRPID	RP.RPREFID	RP.RPSPID	RP.RPLNKI
RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSGRPID	RS.RSREFID	RS.RSSPID	RS.RSLNKI
SC	STUDYID	DOMAIN	USUBJID	SC.SCSEQ	SC.SCGRPID	SC.SCSPID	SC.SCTESTCD	SC.SCTES
SS	STUDYID	DOMAIN	USUBJID	SS.SSSEQ	SS.SSGRPID	SS.SSSPID	SS.SSTESTCD	SS.SSTEST
TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TRREFID	TR.TRSPID	TR.TRLNKI
TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKI
UR	STUDYID	DOMAIN	USUBJID	UR.URSEQ	UR.URGRPID	UR.URREFID	UR.URSPID	UR.URLNK
VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTEST
FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST
SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTES
CO	STUDYID	DOMAIN	RDOMAIN	USUBJID	CO.COSEQ	CO.IDVAR	CO.IDVARVAL	CO.COREF
DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC	DM.RFXSTDTC	DM.RFXEN
SE	STUDYID	DOMAIN	USUBJID	SE.SESEQ	SE.ETCD	SE.ELEMENT	SE.TAETORD	SE.EPOCH
SM	STUDYID	DOMAIN	USUBJID	SM.SMSEQ	SM.MIDS	SM.MIDSTYPE	SM.SMSTDTC	SM.SMEND
SV	STUDYID	DOMAIN	USUBJID	SV.VISITNUM	SV.VISIT	SV.SVPRESP	SV.SVOCCUR	SV.SVREAS
TA	STUDYID	DOMAIN	TA.ARMCD	TA.ARM	TA.TAETORD	TA.ETCD	TA.ELEMENT	TA.TABRAN
TD	STUDYID	DOMAIN	TD.TDORDER	TD.TDANCVAR	TD.TDSTOFF	TD.TDTGTPAI	TD.TDMINPAI	TD.TDMAXF
TE	STUDYID	DOMAIN	TE.ETCD	TE.ELEMENT	TE.TESTRL	TE.TEENRL	TE.TEDUR	
TI	STUDYID	DOMAIN	TI.IETESTCD	TI.IETEST	TI.IECAT	TI.IESCAT	TI.TIRL	TI.TIVERS
TM	STUDYID	DOMAIN	TM.MIDSTYPE	TM.TMDEF	TM.TMRPT			
TS	STUDYID	DOMAIN	TS.TSSEQ	TS.TSGRPID	TS.TSPARMCD	TS.TSPARM	TS.TSVAL	TS.TSVALN
TV	STUDYID	DOMAIN	TV.VISITNUM	TV.VISIT	TV.VISITDY	TV.ARMCD	TV.ARM	TV.TVSTRL
OI	STUDYID	DOMAIN	OI.NHOID	OI.OISEQ	OI.OIPARMCD	OI.OIPARM	OI.OIVAL	
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID	
RELSPEC	STUDYID	USUBJID	REFID	SPEC	PARENT	LEVEL		
RELSUB	STUDYID	USUBJID	POOLID	RSUBJID	SREL			
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
DX	STUDYID	DOMAIN	USUBJID	DX.SPDEVID	DX.DXSEQ	DX.DXGRPID	DX.DXSPID	DX.DXTRT
DE	STUDYID	DOMAIN	USUBJID	DE.SPDEVID	DE.DESEQ	DE.DESPID	DE.DETERM	DE.DEMOD
DT	STUDYID	DOMAIN	DT.SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY	DT.DTDECOD	DT.DTCAT
DU	STUDYID	DOMAIN	USUBJID	DU.SPDEVID	DU.DUSEQ	DU.DUGRPID	DU.DUREFID	DU.DUSPI
DO	STUDYID	DOMAIN	DO.SPDEVID	DO.DOSEQ	DO.DOGRPID	DO.DOREFID	DO.DOSPID	DO.DOTES
DR	STUDYID	DOMAIN	USUBJID	DR.SPDEVID				
DI	STUDYID	DOMAIN	DI.SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM	DI.DIVAL	

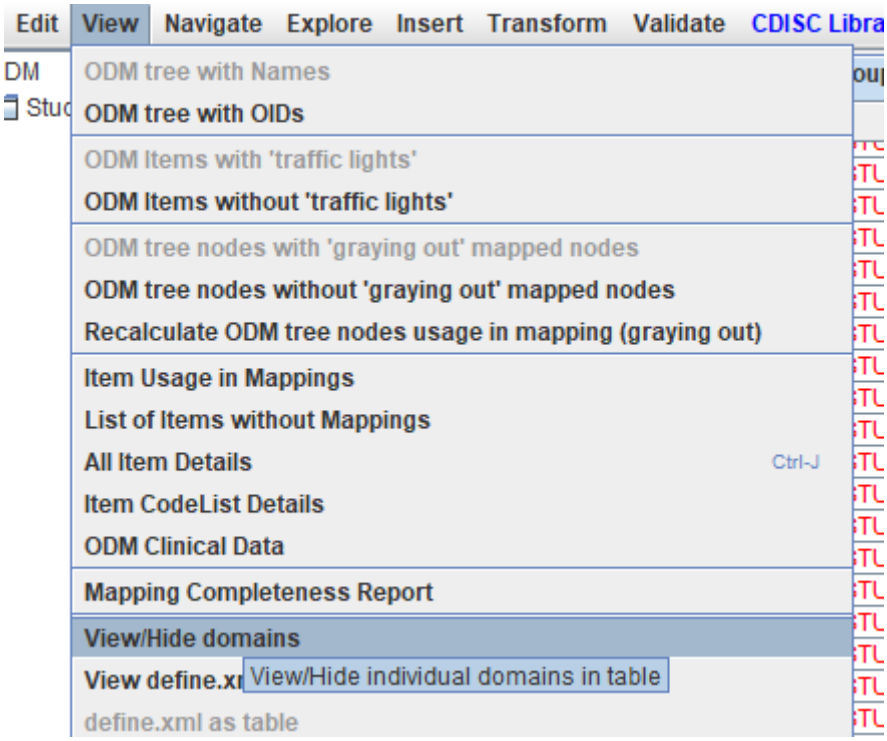
with the "regular" SDTM domains in the upper part and the MD domains in the lower part.

P.S. If one later also wants to be able to have "non-standard variables" for one of the MD domains, and wants to have split these of to SUPPxx datasets (e.g. SUPPDT), one must also a template for a "regular" SDTMIG version loaded, as for generating the SUPPxx dataset, the system requires metadata from the (generic) SUPPQUAL dataset definition from the template.

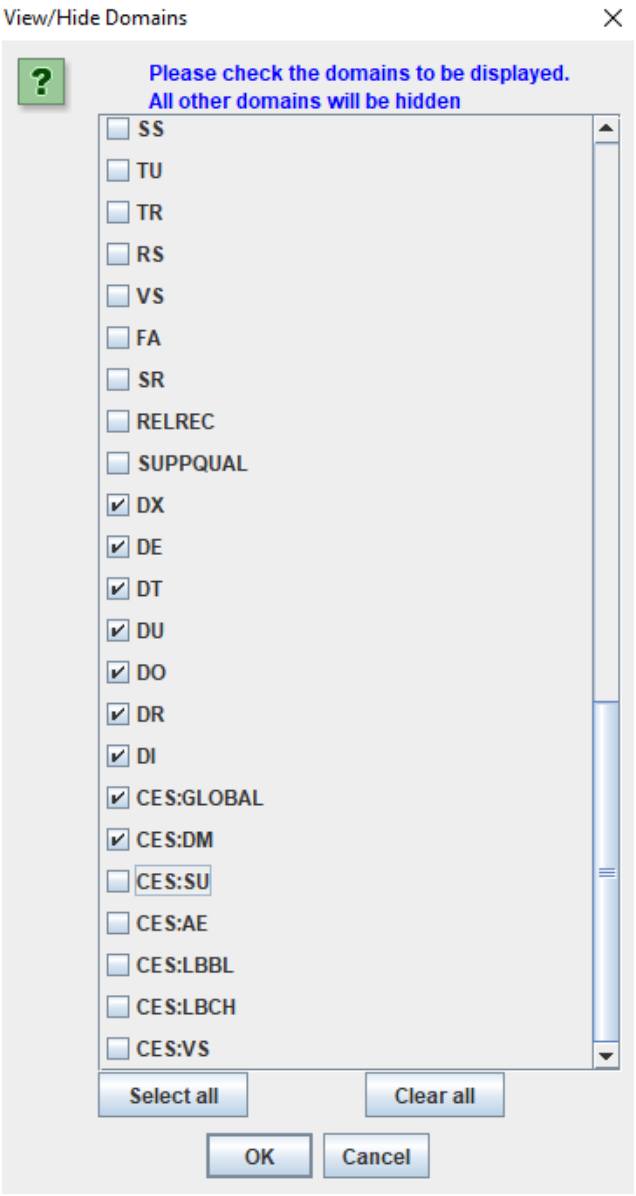
It is of course also possible to additionally load the MD domains to the mappings of an existing study. To do so, one can use the menu "File - Load template define.xml" again, and navigate to the folder with the template domains (named "define_2_1" or "define_2_0") and then select the template file for the Medical Devices domain version.
Reason for this is that one often also wants to have the (already existing) mappings for the DM domain, and possibly a "GLOBAL" set of mappings that can be used in any domain. For example:

VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTE
FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATES
SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTE
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID	
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
DX	STUDYID	DOMAIN	USUBJID	DX.SPDEVID	DX.DXSEQ	DX.DXGRPID	DX.DXSPID	DX.DXTR
DE	STUDYID	DOMAIN	USUBJID	DE.SPDEVID	DE.DESEQ	DE.DESPID	DE.DETERM	DE.DEMC
DT	STUDYID	DOMAIN	DT.SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY	DT.DTDECOD	DT.DTCA
DU	STUDYID	DOMAIN	USUBJID	DU.SPDEVID	DU.DUSEQ	DU.DUGRPID	DU.DUREFID	DU.DUSF
DO	STUDYID	DOMAIN	DO.SPDEVID	DO.DOSEQ	DO.DOGRPID	DO.DOREFID	DO.DOSPID	DO.DOTE
DR	STUDYID	DOMAIN	USUBJID	DR.SPDEVID				
DI	STUDYID	DOMAIN	DI.SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM	DI.DIVAL	
CES:GLOBAL	REFSTARTDATE							
CES:DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC	DM.RFXSTDTC	DM.RFXE
CES:SU	STUDYID	DOMAIN	USUBJID	SU.SUSEQ	SU.SUGRPID	SU.SUSPID	SU.SUTRT	SU.SUMC
CES:AE	STUDYID	DOMAIN	USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID	AE.AESPID	AE.AETE
CES:LBBL	STUDYID	DOMAIN	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTE
CES:LBCH	STUDYID	DOMAIN	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTE
CES:VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTE

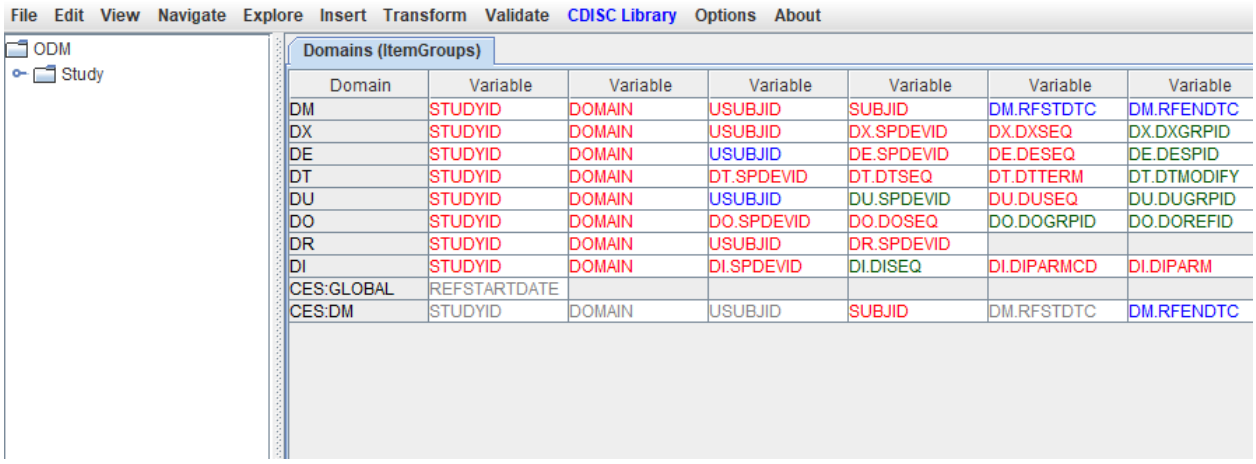
As the screen is now overloaded with information, one can decide to hide a good number of domain, especially those of the templates that one does not want to use for the moment, using the menu "View - View/Hide domains":



and then select the ones that one wants to keep visible, e.g.:



then leading to e.g.:



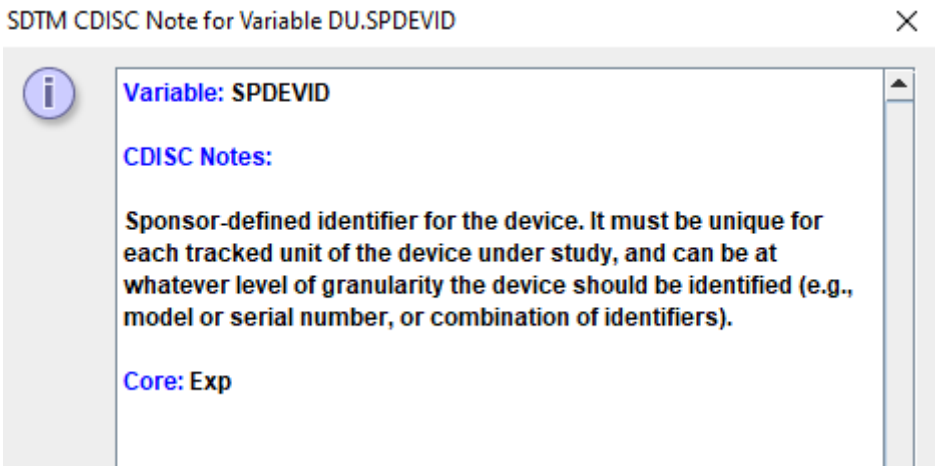
Domain	Variable	Variable	Variable	Variable	Variable	Variable
DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC
DX	STUDYID	DOMAIN	USUBJID	DX.SPDEVID	DX.DXSEQ	DX.DXGRPID
DE	STUDYID	DOMAIN	USUBJID	DE.SPDEVID	DE.DESEQ	DE.DESPID
DT	STUDYID	DOMAIN	DT.SPDEVID	DT.DTSEQ	DT.DTTERM	DT.DTMODIFY
DU	STUDYID	DOMAIN	USUBJID	DU.SPDEVID	DU.DUSEQ	DU.DUGRPID
DO	STUDYID	DOMAIN	DO.SPDEVID	DO.DOSEQ	DO.DOGRPID	DO.DOREFID
DR	STUDYID	DOMAIN	USUBJID	DR.SPDEVID		
DI	STUDYID	DOMAIN	DI.SPDEVID	DI.DISEQ	DI.DIPARMCD	DI.DIPARM
CES:GLOBAL	REFSTARTDATE					
CES:DM	STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC

which is considerably easier to handle.

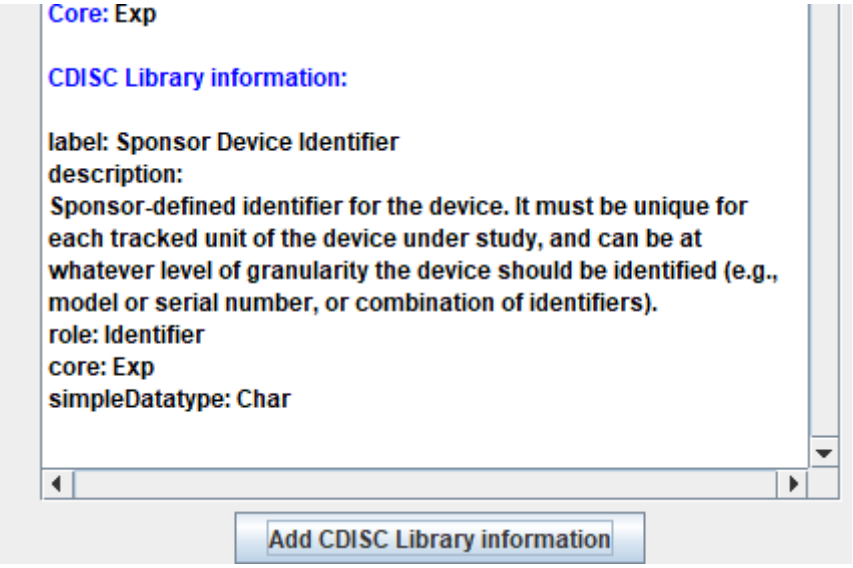
We can now generate "study-specific instances" of the MD domains by drag-and-drop, or by mouse

selection and using the menus "Edit - Copy domain/dataset" and "Edit - Paste domain/dataset".

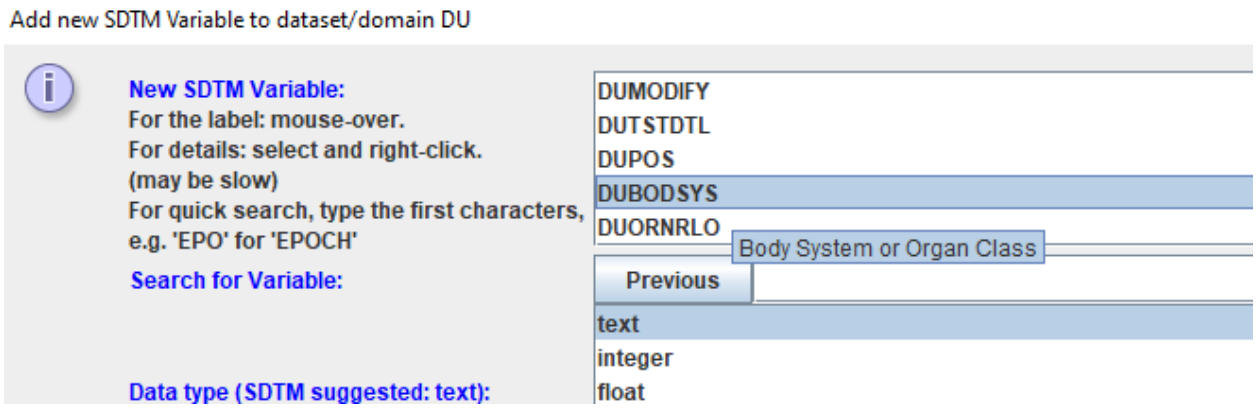
As usual, we can now also get information about a single variable by selecting its cell and using the menu "View – SDTM CDISC Notes" (or using CTRL-H). For example for "SPDEVID" in "DU":



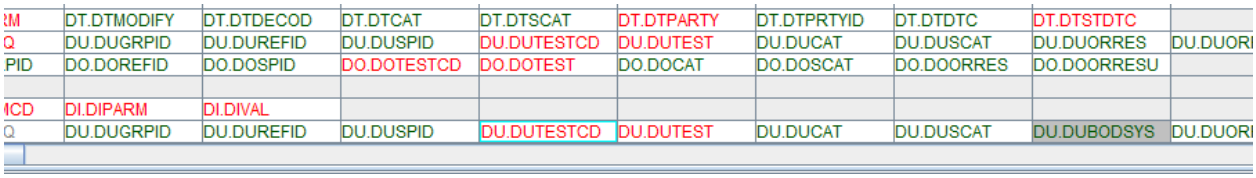
and when also asking for additional CDISC Library information (requires an API key in your "properties.dat" file):



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":



may give a warning that "DUBODSYS" would not generally be used in this domain". If this happens, and one clicks "Ignore", the variable is added, e.g.:



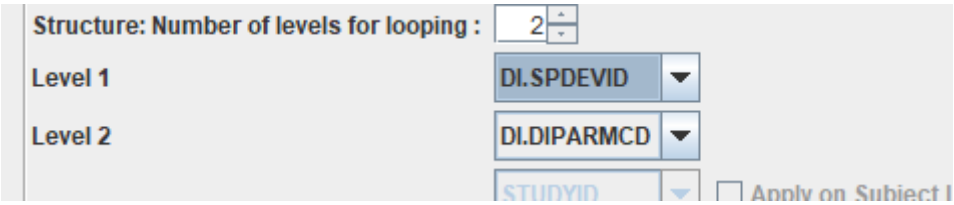
M	DT.DTMODIFY	DT.DTDECOD	DT.DTCAT	DT.DTSCAT	DT.DTPARTY	DT.DTPRTYID	DT.DTDTC	DT.DTSTDTC	
Q	DU.DUGRPID	DU.DUREFID	DU.DUSPID	DU.DUTESTCD	DU.DUTEST	DU.DUCAT	DU.DUSCAT	DU.DUORRES	DU.DUORI
PID	DO.DOREFID	DO.DOSPID	DO.DOTESTCD	DO.DOTEST	DO.DOCAT	DO.DOSCAT	DO.DOORRES	DO.DOORRESU	
CD	DI.DIPARM	DI.DIVAL							
Q	DU.DUGRPID	DU.DUREFID	DU.DUSPID	DU.DUTESTCD	DU.DUTEST	DU.DUCAT	DU.DUSCAT	DU.DUBODSYS	DU.DUORI

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

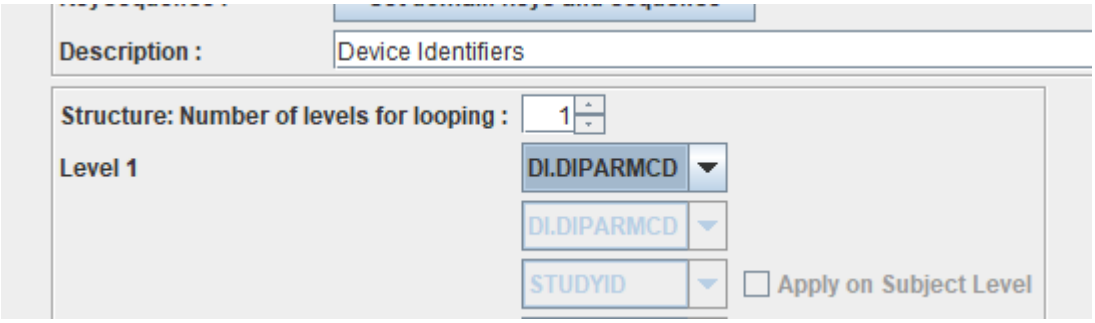
Selecting a suitable "looping variable"

Depending on the structure of your data in the ODM tree, you may want to change the defaults for the "looping parameter", which defines the SDTM variable or sets of SDTM variables steer how the records are set up in the SDTM result.

When one double-clicks the "DI" cell in the "study-specific" instance (by drag-and-drop from the template), or select the cell and use the menu "Edit - SDTM Dataset Definition Properties" one will find:



Essentially stating that "one record per item representing DIPARMCD in the ODM tree per item representing SPDEVID in the ODM tree" will steer the generation of the records.
Depending on the structure of these in the ODM tree, it may often be sufficient to set DIPARMCD as the "looping variable", meaning that for each item found representing (or mapping to) DIPARMCD in the ODM tree, a record will be generated.
One can then set "Number of levels for looping" to "1", and just keep "DIPARMCD". For example:



In most cases, it is advantageous to keep the "looping" structure as simple as possible, meaning:

SDTM class	"Looping" variables
Interventions	USUBJID, --TRT
Events	USUBJID, --TERM
Findings	USUBJID, --TESTCD

Some of the Medical Device domains do not have USUBJID, but do have SPDEVID (Device Identifier)

DI however has the class "Study Reference" …

So, the default "Looping" variables for the Medical Devices domains are:

Domain	Class	"Looping" variables
DI (Device Identifiers)	Study Reference	SPDEVID, DIPARMCD
DX (Device Exposure)	Exposure	USUBJID, DXTRT
DT (Device Trackings and Disposition)	Events	SPDEVID, DTTERM
DE (Device Events)	Events	USUBJID, DETERM
DU (Device-In-Use)	Findings	USUBJID, DUTESTCD
DO (Device Properties)	Findings	SPDEVID, DUTESTCD
DR (Device-Subject Relationships)	Relationship	SPDEVID, USUBJID

Depending on how the data is organized in the ODM tree, one can of course change this. Especially, as in ODM data is not organized by device, but by subject, it can sometimes, or even often, be advantageous to remove "SPDEVID" from the "looping parameter".