## SDTM-ETL 3.0 User Manual and Tutorial

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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 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:

SDTM-ETL - version 3.0	and with the	and the other	and a final se							
File Edit View Navigate Insert Transform Validate Op 특히 이어씨	btions About	Croupe)								
	Domains (iten	nGroups)								
φ- <u></u> Study	Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	V
• GlobalVariables	SV	STUDYID	DOMAIN	USUBJID	SV.VISITNUM	SV.VISIT	SV.VISITDY	SV.SVSTDTC	SV.SVENDTC	SV.SV: 4
<ul> <li>BasicDefinitions</li> </ul>	CM	STUDYID	DOMAIN	USUBJID	CM.CMSEQ	CM.CMGRPID	CM.CMSPID	CM.CMTRT	CM.CMMODIFY	CM.CN
P C MetaDataVersion : Version 1.1.0	EC	STUDYID	DOMAIN	USUBJID	EC.ECSEQ	EC.ECGRPID	EC.ECREFID	EC.ECSPID	EC.ECLNKID	EC.EC
🗠 🗂 Protocol	EX	STUDYID	DOMAIN	USUBJID	EX.EXSEQ	EX.EXGRPID	EX.EXREFID	EX.EXSPID	EX.EXLNKID	EX.EX
🗢 🔚 CodeList : AE Action Taken, Study Drug	PR	STUDYID	DOMAIN	USUBJID	PR.PRSEQ	PR.PRGRPID	PR.PRSPID	PR.PRLNKID	PR.PRLNKGRP	PR.PR
- Codel ist AF Action Taken Other	SU	STUDYID	DOMAIN	USUBJID	SU.SUSEQ	SU.SUGRPID	SU.SUSPID	SU.SUTRT	SU.SUMODIFY	SU.SU
Codel ist : AE Outcome	AE	STUDYID	DOMAIN	USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID	AE.AESPID	AE.AETERM	AE.AEI
CodeList: AE Belationship to Study Drug	CE	STUDYID	DOMAIN	USUBJID	CE.CESEQ	CE.CEGRPID	CE.CEREFID	CE.CESPID	CE.CETERM	CE.CE
CodeList: AE Relationship to Study Drug	DV	STUDYID	DOMAIN	USUBJID	DV.DVSEQ	DV.DVREFID	DV.DVSPID	DV.DVTERM	DV.DVDECOD	DV.DV
CodeList: AE Severity	HO	STUDYID	DOMAIN	USUBJID	HO.HOSEQ	HO.HOGRPID	HO.HOREFID	HO.HOSPID	HO.HOTERM	HO.HC
CodeList : Assigned Study Drug	DS	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DS
🗢 🔚 CodeList : Record Status, Internal	MH	STUDYID	DOMAIN	USUBJID	MH.MHSEQ	MH.MHGRPID	MH.MHREFID	MH.MHSPID	MH.MHTERM	MH.MF
🕶 🗂 CodeList : Normal/Abnormal/Not Done	DA	STUDYID	DOMAIN	USUBJID	DA.DASEQ	DA.DAGRPID	DA.DAREFID	DA.DASPID	DA.DATESTCD	DA.DA
🕶 🗂 CodeList : PE Body System	DD	STUDYID	DOMAIN	USUBJID	DD.DDSEQ	DD.DDTESTCD	DD.DDTEST	DD.DDORRES	DD.DDSTRESC	DD.DE
🕶 🗂 CodeList : Conmed Regimen	EG	STUDYID	DOMAIN	USUBJID	EG.EGSEQ	EG.EGGRPID	EG.EGREFID	EG.EGSPID	EG.EGTESTCD	EG.EG
CodeList : Conmed Route	IE	STUDYID	DOMAIN	USUBJID	IE.IESEQ	IE.IESPID	IE.IETESTCD	IE.IETEST	IE.IECAT	IE.IES
Codel ist : Country	IS	STUDYID	DOMAIN	USUBJID	IS.ISSEQ	IS.ISGRPID	IS.ISREFID	IS.ISSPID	IS.ISTESTCD	IS.ISTE
CodeList: Conder	LB	STUDYID	DOMAIN	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTESTCD	LB.LB
CodeList: Gendel	MB	STUDYID	DOMAIN	USUBJID	MB.MBSEQ	MB.MBGRPID	MB.MBREFID	MB.MBSPID	MB.MBTESTCD	MB.ME
CodeList: Therapeutic Area	MS	STUDYID	DOMAIN	USUBJID	MS.MSSEQ	MS.MSGRPID	MS.MSREFID	MS.MSSPID	MS.MSTESTCD	MS.MS
CodeList : LOINC Version 2.0	MI	STUDYID	DOMAIN	USUBJID	MI.MISEQ	MI.MIGRPID	MI.MIREFID	MI.MISPID	MI.MITESTCD	MLMIT
🗠 🚞 ReferenceData	MO	STUDYID	DOMAIN	USUBJID	MO.MOSEQ	MO.MOGRPID	MO.MOREFID	MO.MOSPID	MO.MOLNKID	MO.MC
	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.QSSPID	QS.QSTESTCD	QS.QSTEST	QS.QS
	RP	STUDYID	DOMAIN	USUBJID	RP.RPSEQ	RP.RPGRPID	RP.RPREFID	RP.RPSPID	RP.RPTESTCD	RP.RF
	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.SSSPID	SS.SSTESTCD	SS.SSTEST	SS.SS
	TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKID	TU.TU
	TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TRREFID	TR.TRSPID	TR.TRLNKID	TR.TR
	RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSGRPID	RS.RSREFID	RS.RSSPID	RS.RSLNKID	RS.RS
	VS	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VS
	FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST	FA.FA0
	SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTESTCD	SR.SR
	RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID		
	SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIC
										• •

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:

Please m	ake your choice
?	<ul> <li>I want to replace the existing define.xml</li> <li>I want to replace the existing define.xml but first save my work</li> <li>I want to merge with the existing define.xml</li> </ul>
	OK Abbrechen

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:

⊱ Öffnen		X
Suchen <u>i</u> n:	📑 define_2_0	▼ A A B -
define_	_template_SDTM_1.2_PGx_old.xml	define_template_SDTI
🗋 🗋 define	_template_SDTM_1.3.xml	define_template_SENI
🗋 define	_template_SDTM_1.3_Med_Devices.xml	defLabel2Description.
🗋 define	_template_SDTM_1.3_Non_Subject_Data.	kml
📄 🗋 define	_template_SDTM_1.3_old.xml	
define_	_template_SDTM_1.4.xml	
•	II	•
<u>D</u> ateiname:	define_template_SDTM_1.3_Med_Devices	s.xml
Da <u>t</u> eityp:	All Files	▼
		Öffnen Abbrechen

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

	0.0010		0000000	00.00004	00.0001110	00.000110	00.00120100	00.001201	00.000
TU	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKID	TU.TUTESTCI
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.RSLNKGF
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.DEDECOL
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.:

View/Hide Domains	x	View/Hide Domains	x
Please check the domains to be display All other domains will be hidden	ed.	Please check the domains All other domains will be h	to be displayed. idden
✓ DM	<b>^</b>	DM	<b>^</b>
✓ TE		TE	
I TA		TA 🗌	
<b>Ⅲ</b>		П	
VT V		TV	
<b>∠</b> TS	=	TS	=
✓ TD			
<b>I</b> CO			
✓ SE		FA	
✓ SV		SR	
CM			
✓ EC			
✓ EX			
PR			=
⊮ SU			
I AE			
✓ CE			
✓ DV			
IN HO			<b>_</b>
✓ DS		Select all C	lear all
MH MH			
I DA			
✓ DD	-		
Select all Clear all			
OK Abbrechen			

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

## This leads to:

SDTM-ETL - version 3.0	-							
File Edit View Navigate Insert Transform	Validate Option	ns About						
	Domains (Item)	Groups)						
⊶ ⊡ Study	Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable
- ReferenceData	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":

SDTM CD	DISC Note for Variable SPDEVID	23
i	Sponsor-defined identifier for a device	

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":

Add new SDTM Variable to domain DU					
(i) New SDTM Variable:	DU.DUMODIFY DU.DUTSTDTL DU.DUPOS DU.DUBODSYS DU.DUORNRLO				
Data type (SDTM suggested: text):	text integer float datetime date	Body System or Organ Class			

we will get the following warning:

Warning	X
	According to the SDTM-IG The qualifier DUBODSYS would not generally be used in this domain
	Ignore Cancel

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:

1	Doma	ins (ItemGroups)							
	ble	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Vai
	ID	DU.DUTESTCD	DU.DUTEST	DU.DUCAT	DU.DUSCAT	DU.DUBODSYS	DU.DUORRES	DU.DUORRESU	DU.DUS
	Γ	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.