SDTM-ETL 4.4 User Manual and Tutorial

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Ensuring Mapping Completeness

Table of Contents

Table of Contents	1
Introduction	1
"Graying out" used items from the ODM	1
"Highlighting" of SDTM/SEND cells	6
Using the menu "View - Item Usage in Mappings"	
Using the menu "View - List Items not used in Mappings"	
Basic information when executing mappings	11
Mapping Completeness for Hypervertical ODM Structures	
Checking completeness on the SDTM side	
Conclusion	

Introduction

Ensuring mapping completeness, i.e. ensuring that all collected (and derived) data that needs to go into the SDTM or SEND, is always a challenge.

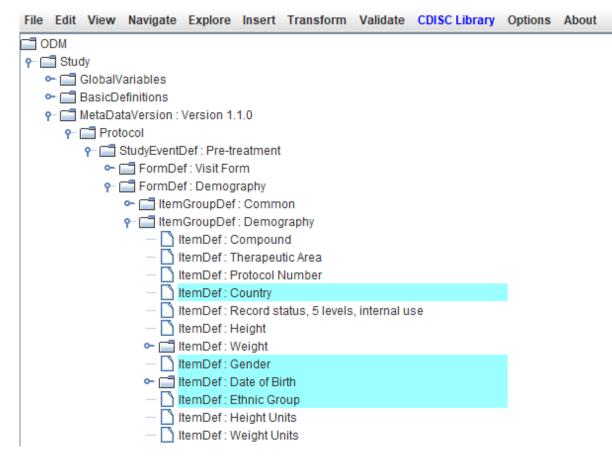
The danger is always that some subjects or visit have been forgotten or skipped, or that some measurements did not make it into the findings datasets. Another typical ones is that measurements for which no results have been obtained, and/or the reason why the measurement did not have results.

The other way around, one may have that one has SDTM/SEND domains and variables for which, based on the input data, one should have mappings for, these domains have not been instantiated as dataset definitions, and/or the variables haven't been provided with a mapping.

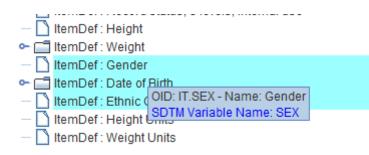
Although SDTM cannot fully guarantee mapping completeness, it has a number of tools allowing the user to check for mapping completeness, and take action when necessary.

"Graying out" used items from the ODM

The loaded ODM defines the metadata of the study, and especially the CRFs (in the case of human clinical trials). For example:



with the items (CRF questions) with a cyan background color, having an "**SDTM annotation**" in the ODM, as very often for items in CDASH forms. The SDTM annotation can be seen when hovering the mouse over the item, for example:



or by using the menu "View - All Item Details", e.g. leading to:

Message

i

Details for ItemDef with OID IT.SEX with Name 'Gender' Max. Characters Mapping to SDTM after SASFieldName Data type | Mandatory? | Max. Length decimal variable point 6 SEX text No SEX CodeList with OID CL.SEXF with Name 'Gender' Data type: text Allowed values (code and decode) Coded value NCI Code Decode language Decode 0 en Female 1 Male en

When then clicking on "Gender" and DM has been loaded, the "SEX" SDTM cell will automatically be highlighted and even selected:

DM.AGEU	DM.SEX	DM.RACE	DM.ETHNIC

easing drag-and-drop from ODM "Gender" to SDTM DM.SEX1.

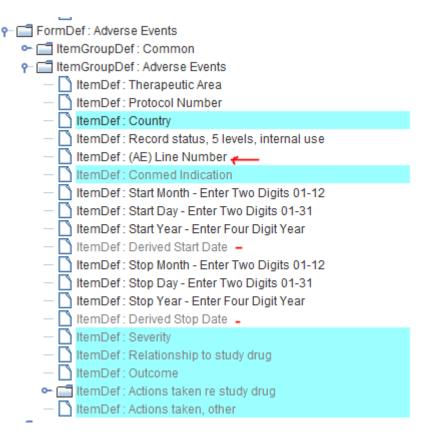
When then having mapped "Gender" to SDTM DM.SEX, one will see that the foreground color changes from black to gray:



i.e. the item "Gender" has been "grayed out", as has being used in an SDTM mapping.

When the mapping has then been advanced, one may e.g. see:

¹ We decided <u>not</u> to automate the drag-and-drop in such a case, as we still want the user to be in charge, and taking all the decisions.



where one sees that "(AE) line number" has not been used in a mapping yet. However, it does not have an SDTM annotation where it should go into in SDTM. Typical usage of "line number" in SDTM is AESPID (Sponsor-defined Identifier), as is also explained in the SDTM-IG:

	I			single domain for a subject.	
AEREFID	Reference ID	Char	Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
AESPID	Sponsor-Defined Identifier	Char		Sponsor-defined identifier. It may be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on an Adverse Events page.	Perm
AFTERM	Reported Term for	Char	Topic	Verbatim name of the event	Rea

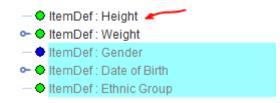
So, when one then drags-and-drops "(AE) Line Number" to the SDTM cell "AESPID" and confirms the mapping, also "(AE) line number" will be "grayed out"²:

- ItemDef : Protocol Number
 ItemDef : Country
 ItemDef : Record status, 5 levels, internal use
 ItemDef : (AE) Line Number
- 🗋 ItemDef : Conmed Indication
- 🗋 ItemDef : Start Month Enter Two Digits 01-12

In the example, one also sees that "Start Month...", "Start Day...", "Start Year..." and similar for "End Month..." have not been used. However, "Derived Start Date" and "Derived End Date" have been used. So it is not always so that an item from the ODM must necessarily flow into SDTM. Typical examples are so-called "cleaning aids" like "Did any adverse event occur".

² Remember that "line number", going into AESPID is often use to connect concomitant medications to an adverse event that caused the medication to be given.

This "graying out" mechanism also works when using multiple items in drag-and-drop, the socalled "generalizations". When for example doing a drag-and-drop for "Height"



to the cell "VSORRES", and then using the "Generalization" to also include "Weight":

🛓 Import	ltemDef: Height - for SD	TM Variable VS	S.VSORRES						\times	SDECOD	DS.DSCAT MH.MHDECOD	DS.DSSCAT MH.MHCAT	DS.EPOCH MH.MHSCAT
?	Import XPath expr	secion for Ito	mData Vali	uo attrik	uto (from Cliv	nical Dat	a)			DATEST DRESCAT	DA.DACAT DD.DDEVAL	DA.DASCAT DD.DDDTC	DA.DAORRE DD.DDDY
	· · ·									GTEST	EG.EGCAT	EG.EGSCAT	EG.EGPOS
	Import XPath expression	ession for an	other Itemi	Data att	ribute/subele	ment (fr	om Clinica	il Data)		SCAT	IE.IEORRES	IE.IESTRESC	IE.VISITNUK
	Import ItemDef attr	ribute value (s	static value	from S	tudy Definitio	n)				TEST	IS.ISCAT	IS.ISSCAT	IS.ISORRES
	Generalize for all	StudyEvonte	Except	for	No Exception		nly for	No Inclusions		BTEST	LB.LBCAT	LB.LBSCAT	LB.LBORRE
		StudyEvents	Except	101	NOException		IIY IOI	NOTICIUSIONS		IBTEST	MB.MBCAT	MB.MBSCAT	MB.MBORR
	Generalize for all F	orms	Except	for	No Exception	is Oi	ily for	No Inclusions		ISTEST	MS.MSCAT	MS.MSSCAT	MS.MSORR
	Generalize for all I	temGroups	Except	for	No Exception		nly for	No Inclusions		TEST IOTESTCD	MI.MITSTDTL MO.MOTEST	MI.MICAT MO.MOCAT	MI.MISCAT MO.MOSCA
							-	1		CTEST	PC.PCCAT	PC.PCSCAT	PC.PCORR
	Generalize for all l	tems	Except	for	No Exception	15 <mark>0</mark> 1	nly for	2 Inclusions		PSCAT	PP.PPORRES	PP.PPORRESU	PP.PPSTRE
	(DDM ItemDef I	Lenghth: 4	SDT	M Variable L	anath 0				EMODIEY	PE PECAT	PE PESCAT	PE PERODO
		Set SDTM	Variable L	ength to	ODM ItemDe	🛓 Incl	usions for	ltemDef					×
	View/Edit XPath ex	pression (adv	vanced)			?	IT.R_	_DRUG - Compo	und				-
		[ОК	Cano		_		REA - Therape	utic	Area			
				Callo			_						
USUB.			GRPID	RS.RS			IT.PI	IO - Protocol Nu	umb	ег			
USUB.	JID VS.VSSEQ	VS.VS	GRPID	VS.VSS	SPID V		IT.SC	CTRY - Country					
USUB.		FA.FAG		FA.FAS			IT.F	STATUS - Reco	ord s	tatus, 5 levels	s, internal use		
USUB.			GRPID	SR.SR	REFID S						, intornal acco		
USUB.		IDVAR'		RELTY	PE R		[№ 11.Н1	F - Height					_
USUB.		IDVAR	STDTC	QNAM	ENDTC D		🖌 IT.W	T - Weight					
USUB.			GRPID	QS.QS				X - Gender					
USUB.		SV.VIS		SV.VIS									
USUB.		PE.PE		PE.PE				DB - Date of Birt	th				
USUB.	JID AE.AESEQ	AE.AE(GRPID	AE.AEF	REFID A		IT.R/	ACE - Ethnic Gro	oup				
USUB.	JID VS.VSSEQ	VS.VS	GRPID	VS.VS	SPID 🚺		П.Н.	UNITS - Height	Unif	s			
•								-					
Name="HT"	- SignificantDigits="1"	·					U 11.W	TUNITS - Weigh	nt Un	lits			-
_										С	lear All		
										ОК	Cancel		

and then doing accepting the mapping, both "Height" and "Weight" will be "grayed out" in the ODM tree:



P.S. Sometimes, this "graying out" may not immediately become visible, and needs another selection with the mouse. One can however also use the menu "View - Recalculate ODM tree nodes usage in mapping":

	View	Navigate	Explore	Insert	Transform	Validate	CDISC Libr				
	ODM tree with Names										
IC	ODM tree with OIDs										
1	ODM Items with 'traffic lights'										
	ODM Items without 'traffic lights'										
• [ODM t	ree nodes	with 'gray	ing out'	mapped node	es					
	ODM tree nodes without 'graying out' mapped nodes										
	Recal	culate ODM	l tree nod	e <mark>s usag</mark>	e in mapping	(graying ou	ut)				
- 1											

Remark: currently, "graying out" only partially works when doing a "negative selection" during the "generalization", e.g. "exclude all items in the group except for 'Height' and 'Weight'. So, for the moment, we recommend to use "positive selections" (i.e. using "Only for ...") as much as possible.

"Highlighting" of SDTM/SEND cells

Once mapped, when selecting an Item in the ODM tree, the system looks up whether the item is used in any of the mappings, and if so, "highlights" the SDTM/SEND cells in which the Item of the ODM tree is used. For example, when clicking "Diastolic BP", the cells "VSTESTCD" and "VSORRES" light up:

	18								
🕶 🚞 ItemGroupDef : Drinking History	RE.REGRPID	RE.REREFID	RE.RESPID	RE.RELNKID	RE.RELNKGRP	RE.RETESTCD	RE.RETEST	RE.REC/	
👇 🗂 ItemGroupDef : Physical Exam	JR.URREFID	UR.URSPID	UR.URLNKID	UR.URLNKGRP	UR.URTESTCD	UR.URTEST	UR.URTSTDTL	UR.URC	
🗢 🗂 Description	PC.PCREFID	PC.PCSPID	PC.PCTESTCD	PC.PCTEST	PC.PCCAT	PC.PCSCAT	PC.PCORRES	PC.PCO	
🕶 🗢 ItemDef : Height	PP.PPTESTCD	PP.PPTEST	PP.PPCAT	PP.PPSCAT	PP.PPORRES	PP.PPORRESU	PP.PPSTRESC	PP.PPST	
⊶ ♦ ItemDef : Weight	PE.PESPID	PE.PETESTCD	PE.PETEST	PE.PEMODIFY	PE.PECAT	PE.PESCAT	PE.PEBODSYS	PE.PEOF	
-	T.FTREFID	FT.FTSPID	FT.FTTESTCD	FT.FTTEST	FT.FTCAT	FT.FTSCAT	FT.FTPOS	FT.FTOR	
• • ItemDef : Systolic BP	2S.QSSPID	QS.QSTESTCD	QS.QSTEST	QS.QSCAT	QS.QSSCAT	QS.QSORRES	QS.QSORRESU	QS.QSS	
ItemDef : Diastolic BP	RS.RSREFID	RS.RSSPID	RS.RSLNKID	RS.RSLNKGRP	RS.RSTESTCD	RS.RSTEST	RS.RSCAT	RS.RSS(
- ItemDef : Dizzyness at low DBF	SC.SCSPID	SC.SCTESTCD	SC.SCTEST	SC.SCCAT	SC.SCSCAT	SC.SCORRES	SC.SCORRESU	SC.SCS	
— 🗋 Alias : [SDTM] : VS	S.SSSPID	SS.SSTESTCD	SS.SSTEST	SS.SSCAT	SS.SSSCAT	SS.SSORRES	SS.SSSTRESC	SS.SSST	
ItemGroupDef: XRay	U.TUREFID	TU.TUSPID	TU.TULNKID	TU.TULNKGRP	TU.TUTESTCD	TU.TUTEST	TU.TUORRES	TU.TUST	
🕶 🗂 ItemGroupDef : Complaints due t	R.TRREFID	TR.TRSPID	TR.TRLNKID	TR.TRLNKGRP	TR.TRTESTCD	TR.TRTEST	TR.TRORRES	TR.TROF	
🗣 📑 FormDef : Prior or Concomitant Medi	/S.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VSCAT	VS.VSSCAT	VS.VSPOS	VS.VSORRES	VS.VSOF	
 FormDef: Laboratory 	A.FASPID	FA.FATESTCD	FA.FATEST	FA.FAOBJ	FA.FACAT	FA.FASCAT	FA.FAORRES	FA.FAOR	
	R.SRREFID	SR.SRSPID	SR.SRTESTCD	SR.SRTEST	SR.SROBJ	SR.SRCAT	SR.SRSCAT	SR.SROI	
- StudyEventDef : Week 1 Visit	A.ETCD	TA.ELEMENT	TA.TABRANCH	TA.TATRANS	TA.EPOCH				
🕶 🛅 StudyEventDef : Week 2 Visit	E.TEENRL	TE.TEDUR							
🗠 📑 StudyEventDef : Patient Diary Event	V.ARMCD	TV.ARM	TV.TVSTRL	TV.TVENRL					
∽ 📑 StudyEventDef: Adverse Event	D.TDTGTPAI	TD.TDMINPAI	TD.TDMAXPAI	TD.TDNUMRPT					
CodeList: Sex									
CodeList: Race	T.IESCAT	TI.TIRL	TI.TIVERS						
CodeList: Smoking	S.TSPARM	TS.TSVAL	TS.TSVALNF	TS.TSVALCD	TS.TSVCDREF	TS.TSVCDVER			
	RELTYPE	RELID							
CodeList : Drinking	SUPPQUAL.QN	SUPPQUAL.QL	SUPPQUAL.QVAL	SUPPQUAL.QO	SUPPQUAL.QE				
CodeList : Diary									
CodeList : Diary Day	DI.OIPARM	OI.OIVAL							
CodeList : No Yes	/S.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VSCAT	VS.VSSCAT	VS.VSPOS	VS.VSORRES	VS.VSOF	
"integer" - Length="3" - Mandatory="Yes" - MethodOID="METH.001" - Name="Diastolic BP" - OID="I_DIABP" - SASFieldName="DIASYSTL" - SDSVarName="VSORRES"									

Remark that when the "decode()" function has been used for VSTEST, like:

```
The Transformation Script

1 # Mapping using the decode() function on codelist CL.C66741.VSTESTCD of variable VS.VSTESTCD

2 $VS.VSTEST = decode($VS.VSTESTCD, 'CL.C66741.VSTESTCD', '');
```

the VSTEST cell will not light up, as there is no "xpath(...) statement in the mapping script that points back to the ODM tree node.

Using the menu "View - Item Usage in Mappings"

If one wants to find out whether an ODM item (corresponding to a question on the CRF in the case of human clinical studies mapped to SDTM), one can use the menu "View - Item Usage in Mappings" after having selected an Item in the ODM tree.

File	Edit	View	Navigate	Explore	Insert	Transform	Validate	CDISC L				
0	DM	ODM t	ree with Na	mes								
	Stuc	ODM tree with OIDs										
		ODM Items with 'traffic lights'										
		ODM Items without 'traffic lights'										
	•	ODM tree nodes with 'graying out' mapped nodes										
		ODM tree nodes without 'graying out' mapped nodes										
		Recalculate ODM tree nodes usage in mapping (graying out)										
		Item Usage in Mappings										
		List of	f Items with	out Mapp	ings							

This e.g. leads to:

Message	:	×
i	The ODM ItemDef with OID = IT.SEX and Name = Gender is used in the following SDTM mappings:	
	MyStudy:DM - DM.SEX	
	OK	

It can of course be that a list is provided when the Item has been used in mappings to different SDTM variables, e.g.:

Message	×	
i	The ODM ItemDef with OID = IT.HT and Name = Height is used in the following SDTM mappings: MyStudy:VS - VS.VSTESTCD MyStudy:VS - VS.VSORRES	
	OK	

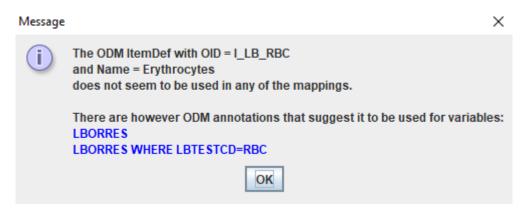
A limitation here still is that when one "reuses" the mapping in another variable, it will not be listed here. For example, when for VSSTRESC (standardized result) one has:

```
The Transformation Script
```

VSSTRESC will not appear in the list from "Item Usage in Mappings"³.

When no mapping is found the message shown is:

When no mapping is found, but the ODM item has one or more annotations (using the "SDSVarName" attribute and/or "Alias/@Context='SDTM" child element), the message shown is e.g.:



Using the menu "View - List Items not used in Mappings"

This feature essentially just works the other way around as "View - Item Usage in Mappings".

It e.g. leads to the list:

³ The reason is that the algorithm is based on the presence of an "xpath(....)" statement in the mapping script.

Message

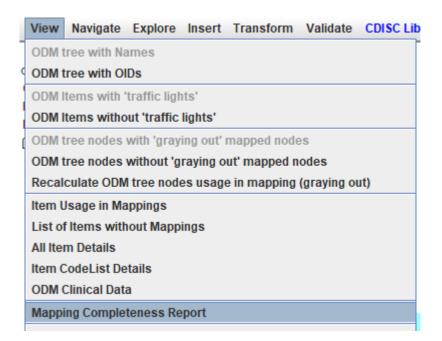
i	Below is a list of items for which there is no direct mapping to SDTM.							
	The occurrence of a collected item in this list does not necessarily mean that the menning is incorrect or incomplete.							
	that the mapping is incorrect or incomplete. The list can however be used to check which items still require mapping to SDTM.							
	IT. SUBJECTID - Subject ID							
	IT.VISTIME - Visit time							
	IT.VISDATETIME - Visit datetime							
	IT.R DRUG - Compound							
	IT.TAREA - Therapeutic Area							
	IT.PNO - Protocol Number							
	IT.F_STATUS - Record status, 5 levels, internal use							
	IT.HTUNITS - Height Units							
	IT.WTUNITS - Weight Units							
	IT.DRUG_COMMENT - Comment IT.PKYR0 - Pretreatment yr							
	IT.PKYR1 - 1-h year							
	IT.PKYR2 - 2-h year							
	IT.PKYR3 - 3-h year							
	IT.PKYR4 - 4-h year							
	IT.PKYR8 - 8-h year							
	IT.PKYR16 - 16-h year							
	IT.PKYR24 - 24-h year							
	IT.MEALYR - Meal year							
	IT.PKMON0 - Pretreatment mon	-						
	OK							

Being in the list does however not mean that the mappings are incomplete or incorrect. For example, we see that "Subject ID" is in the list, but we used the function "usubjid()" in the mappings to retrieve the value of the "SubjectKey" in the ODM clinical data to populate USUBJID. Also, we see that "Height Units" and "Weight Units" is in the list, but these may have been hardcoded, or have been retrieved from the ODM "MeasurementUnit" in the clinical data.

However, it is still always a good idea to go over the list, and ask oneself "do I need this in a mapping, or did I already cover it in another way?"

Generating a full Mapping Completeness Report

Another way to get a good overview of what is already completed and was still needs to be done, is to generate and display a "mapping completeness report", which can be achieved through the menu "View - Mapping Completeness Report":



The user is then asked:

View Ma	pping Completeness Report	\times						
?	Use ODM tree of items							
	○ Use items from ODM CodeList (e.g. for hypervertical structures)							
	Store statistics as CSV							
	Store mapping report as XML							
	OK Cancel							

We will explain the choice "Use items from ODM CodeList (e.g. for hypervertical structures) later, in the section "Mapping Completeness for Hypervertical ODM Structures".

The feature "Store statistics as CSV" can e.g. be used to import in an Excel worksheet for discussion with the team. Similarly, the mapping report can be stored as XML for further processing.

The result will e.g. be:

Me	55	ag	
(ī)	

lapping information is supplied for each ODM Item for which the value of the Value attribute has been used in a mapping									
StudyEvent OID (Name)	Form OID (Name)	ItemGroup OID (Name)	Item OID (Name)	(SDTM) Variable OID	Mapping script				
SE.VISIT0 (Pre-treatment)	FORM.VISIT (Visit Form)	IG.VISIT (Visit basic data)	IT.SITE (Site ID)	DM.SITEID	# SiteID taken from Visit form of first visit (pre-treatment visit) SDM SITEID = ypath(StudyEventOtal_@StudyEventOtD=SE VISIT0']FormData[@FormOID=FORM.VISIT]ItemGroupData[@ItemGroupOID=IG.VISIT]ItemData[@Item				
SE.VISIT0 (Pre-treatment)	FORM.VISIT (Visit Form)	IG.VISIT (Visit basic data)	IT.SUBJECTID (Subject ID)						
SE.VISITO (Pre-treatment)	FORM.VISIT (Visit Form)	IG.VISIT (Visit basic data)	IT.VISDATE (Visit date)	DMRFSTDTC	<pre>SDM.EPSTDTC = ypath(StudyEventData@StudyEventOID=SE.VISIT0}FormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@Item Reference end date taken as visit date from last visit (post-treatment visit) SDM.RFENDTC = ypath(StudyEventData@StudyEventOID=SE.VISIT0}FormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@Item Brithdate taken from Demographics from SIRETUDATE = ypath(StudyEventData@StudyEventOID='SE.VISIT0}FormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.DEMOG']ItemData@ VISITDATE = ypath(StudyEventData@StudyEventOID='SE.VISIT0}FormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@Item G for the difference between the dates as a number of days d addeff gress the date difference as number of days if the for function transforms to an number of days if the foor function transforms to an imteger SAGE = foor(SAGEDAXY's / 365.2); SDM.AGE = ASAE:QSQ.SDTC = ypath(StudyEventDataFormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@ItemOID='IT.VISDATF']@Value);S ypath(StudyEventDataFormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@ItemOID='IT.VISDATF']@Value);S ypath(StudyEventDataFormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@ItemOID='IT.VISDATF']@Value);S ypath(StudyEventDataFormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@ItemOID='IT.VISDATF']@Value);S YPAH(StudyEventDataFormData@FormOID=FORM.VISIT7]ItemGroupData@ItemGroupOID='IG.VISIT7]ItemData@ItemOID='IT.VISDATF']@Value);S YFRETVISITDATE = 'STUTYFYISITDATE' YFRETVISITDATE = 'STUTYFYISITDATE' YFRETVISITDATE = 'STUTYFYISITDATE' 'For the AE start date and start of AE start date YFRETVISITDATE = 'STUTYFYISITDATE' 'For the AE start date, we use the already defined variable ! 'For the AE start date, we use the already defined variable ! 'For the AE start date, we use the already defined variable ! 'For the AE start date, we use the already defined variable ! 'For the AE start date, we u</pre>				

and further on:

		1	0		
					SAE AEENDY = ";)# Mapping using ODM element ItemData with ItemOID II.VISDATE SVS.VSDTC = yath(StudyEventData[@StudyEventOID='SE.VISIT0']FormData[@FormOID='FORM.VISIT']/ItemGroupData[@ItemGroupOID='IG.VISIT']/ItemData[@
SE.VISIT1 (Post-treatment)	FORM.VISIT (Visit Form)	IG.VISIT (Visit basic data)	IT.VISTIME (Visit time)		
SE.VISIT1 (Post-treatment)	FORM.VISIT (Visit Form)	IG.VISIT (Visit basic data)	IT.VISDATETIME (Visit datetime)		
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.COMMON (Common)	IT.SITE (Site ID)	DM.SITEID	# SinD taken from Visit form of first visit (pre-treatment visit) SDM SITEID = spath(ShudyEvenData[@StudyEvenOID='SE.VISIT0']FormData[@FormOID=FORM.VISIT']ItemGroupData[@ItemGroupOID='IG.VISIT']ItemData[@
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.COMMON (Common)	IT.SUBJECTID (Subject ID)		
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.TAREA (Therapeutic Area)		
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.PNO (Protocol Number)		
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.SCTRY (Country)	DM.COUNTRY	SDM.COUNTRY = xpath(StudyEventData[@StudyEventOID='SE.VISIT0']FormData[@FormOID='FORM.DEMOG']/ItemGroupData[@ItemGroupOID='IG.DEMOG']/ItemData
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.F_STATUS (Record status, 5 levels, internal use)		
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.LINE_NO ((AE) Line Number)	AE.AESPID	# Mapping using ODM element ItemData with ItemOID IT.LINE_NO SAE.AESPID = yank/StudyEvenData[@StudyEventOID='SE VISIT1'] FormData[@FormOID=FORM.AE']ItemGroupData[@ItemGroupOID='IG.AE']ItemData[@ItemOI
SE.VISIT1 (Post-treatment)	FORM.AE (Adverse Events)	IG.AE (Adverse Events)	IT.AETERM (Conmed Indication)	AE.AETERM	# Mapping using ODM element ItemData with ItemOID IT.AFTERM # Generalized for all StudyEventS SEA AFTERM - spadh(StudyEventDataFormData[@FormOID=FORM.AE']ItemGroupData[@ItemGroupOID='IG.AE']ItemData[@ItemOID='IT.AFTERM element ItemData with ItemOID IT.AFTERM # Generalized for all StudyEventS SEA AEDECOD - spath(StudyEventDataFormData[@FormOID=FORM.AE']ItemGroupData[@ItemGroupOID='IG.AE']ItemData[@ItemOID='IT.AFTERM # AEAEDECOD - spath(StudyEventDataFormData]@FormOID=FORM.AE']ItemGroupData[@ItemGroupDID='IG.AE']ItemData]@ItemOID='IT.AFTERM # Generalized for all StudyEventDataFormData[@FormOID=FORM.AE']ItemGroupData[@ItemGroupDID='IG.AE']ItemData]@ItemOID='IT.AFTERM # Generalized for all StudyEventDataFormData[@FormOID='FORM.AE']ItemGroupData[@ItemGroupDID='IG.AE']ItemData[@ItemOID='IT.AFTERM # Generalized for all StudyEventDataFormData[@FormOID=FORM.AE']ItemGroupData[@ItemGroupDID='IG.AE']ItemData[@ItemOID='IT.AFTERM # Generalized for all StudyEventDataFormData[@FormOID='IT.AFTERM # Generalized for all StudyEventDataFormData[@ItemGroupDID='IT.AFTERM # Generalized for all StudyEventDataFormData[@ItemGroupDID='IT.AFTERM # Generalized for all StudyEventDataFormFormDataFormDataFormDataFormDataFormFormDataFormDataFormDataFormDataFormDataFormDataFormDataFormDataFo

The absence of any mapping for "Visit date" and "Visit Time" may trigger the idea that one still needs to develop an SV (Subjects Visits) dataset, where these two items will typically be used.

Also here, the absence of a mapping script for an item does not mean that something is wrong, as another method (e.g. hard-coded, copy from another variable) may have been used to develop the mapping.

This report (it is HTML) can then be saved to file using "Save HTML", e.g. for sharing and discussions with the team.

Basic information when executing mappings

New, and somewhat experimental in SDTM-ETL v.4.4 is that when executing the mappings, one also get basic information about the dataset generated that can be used to check whether the mapping, regarding the scope, is complete.

For example when executing the mappings for our example, one may get for DM:

	MyStudy:QS	MyStudy:SV MyStudy:	PE MyStudy:AE My	Study:VS	
STUDYI	D D	OMAIN USUE	BJID SUBJ	ID DM.RFSTDTC	DM.RFEND1
MyStudy	DM	001	001	2006-04-01	2006-05-12
MyStudy	DM	002	002	2006-04-02	2006-05-02
MyStudy	DM	003	003	2006-04-03	2006-05-03
MyStudy	DM	004	004	2006-04-04	2006-05-04
MyStudy	DM	005	005	2006-04-04	2006-05-05
MyStudy	DM	006	006	2006-04-06	2006-05-06
MyStudy	DM	007	007	2006-04-07	
MyStudy	DM	008	008	2006-04-08	2006-05-08
MyStudy	DM	009	009	2006-04-09	2006-05-09
MyStudy	DM	010	010	2006-04-10	2006-05-10
MyStudy	DM	011	011	2006-04-11	2006-05-11
MyStudy	DM	012	012	2006-04-12	2006-05-12
•					
Numerican states					
Number of reco)			
Number of reco Number of subj)			
)			
)			
)			
)			
)			
)			
)			
	ects: 12	You can move columns, re	neiro thom		

providing information about the number of records and subjects. And for VS:

🛓 SDTM Tables

MyStudy:DM M	yStudy:QS MyStudy:S	V MyStudy:PE My	Study:AE My Study:VS			
STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSTESTCD	VS.VSTEST	
MyStudy	VS	001	1	HEIGHT	Height	-
MyStudy	VS	001	2	WEIGHT	Weight	
MyStudy	VS	002	1	HEIGHT	Height	
MyStudy	VS	002	2	WEIGHT	Weight	
MyStudy	VS	003	1	HEIGHT	Height	=
lyStudy	VS	003	2	WEIGHT	Weight	
/lyStudy	VS	004	1	HEIGHT	Height	
MyStudy	VS	004	2	WEIGHT	Weight	
MyStudy	VS	005	1	HEIGHT	Height	
MyStudy	VS	005	2	WEIGHT	Weight	
MyStudy	VS	006	1	HEIGHT	Height	
MyStudy	VS	006	2	WEIGHT	Weight	
MyStudy	VS	007	1	HEIGHT	Height	
MyStudy	VS	007	2	WEIGHT	Weight	
1						Þ
umber of subjects umber of visits: 1 umber of distinct tr arliest value of VSI atest value of VSD	ests: 2 DTC: 2006-04-01					
		ve columns, resize the ng by clicking on the co		t current table		

providing information about the number of records, subjects, visits covered, distinct tests (based on VSTESTCD) and earliest and latest value for VSDTC.

This kind of information helps to answer questions one would regularly need to ask oneself:

- are all subjects covered?
- are all visits covered?
- did I include all tests for this domain?
- is the envisaged time span of the trial covered?

Especially not having all visits and tests covered is a usual problem.

For "Interventions", the number of distinct values of the --TRT (treatment), for "Events", the number of distinct values of "--TERM" (Event term) will be provided.

Mapping Completeness for Hypervertical ODM Structures

In some cases, especially when the data does not come from an EDC system, one may have an ODM file having a "hypervertical" structure, i.e. each "record" (ItemGroup) will come as a "parameter - attributes - value" system. For example:

```
<ItemGroupData ItemGroupOID="IG.DEFAULT" ItemGroupRepeatKev="76">
   <ItemData ItemOID="IT.ScreeningNr" Value="3"/>
   <ItemData ItemOID="IT.ExpDelta" Value="-84"/>
   <ItemData ItemOID="IT.ActDelta" Value="-121"/>
   <ItemData ItemOID="IT.ActClock" Value="21NOV22:08:31:00"/>
   <ItemData ItemOID="IT.Activity" Value="Vitals"/>
   <ItemData ItemOID="IT.Parameter" Value="DiastBPsup"/>
   <ItemData ItemOID="IT.Parameter description" Value="Diastolic blood pressure in supine position"/>
   <ItemData ItemOID="IT.Value" Value="65"/>
   <ItemData ItemOID="IT.Unit" Value="mmHg"/>
   <ItemData ItemOID="IT.Parameter_LowerLimit" Value="50"/>
   <ItemData ItemOID="IT.Parameter_UpperLimit" Value="90"/>
</ItemGroupData>
<ItemGroupData ItemGroupOID="IG.DEFAULT" ItemGroupRepeatKey="77">
   <ItemData ItemOID="IT.ScreeningNr" Value="3"/>
   <ItemData ItemOID="IT.ExpDelta" Value="-84"/>
   <ItemData ItemOID="IT.ActDelta" Value="-121"/>
   <ItemData ItemOID="IT.ActClock" Value="21NOV22:08:31:00"/>
   <ItemData ItemOID="IT.Activity" Value="Vitals"/>
   <ItemData ItemOID="IT.Parameter" Value="HRsup"/>
   <ItemData ItemOID="IT.Parameter description" Value="Heart rate in supine position"/>
   <ItemData ItemOID="IT.Value" Value="48"/>
   <ItemData ItemOID="IT.Unit" Value="bpm"/>
   <ItemData ItemOID="IT.Parameter LowerLimit" Value="45"/>
   <ItemData ItemOID="IT.Parameter UpperLimit" Value="100"/>
</ItemGroupData>
```

providing two measurements, one for diastolic blood pressure and one for heart rate. In "normal" ODM, this would be something like

and one could use the usual "drag-and-drop" mechanism.

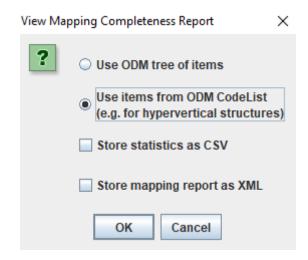
One can of course try to convert one presentation into the other one, but this may be pretty tricky.

Usually, all the parameter values (for "IT.Parameter" and/or for "IT.Parameter_description" are in an ODM codelist. This is e.g. the case when the ODM is generated by our "ODMGenerator" software, which allows to generate ODM files (as well metadata as clinical data) starting from any tabular data such as CSV (possibly extracted from Excel), lab transfers (e.g CDISC Lab), SAS-XPT, etc..

When the ODM data come as "hypervertical", i.e. as "parameter - attributes - value" "records", checking mapping completeness is a bit more difficult.

One can then still make a lot of use of the feature to generate and display a "Mapping Completeness Report". So when using the menu,

and checking the radiobutton "Use Items from ODM CodeList":



one will then be asked which codelist to use (there may be several), for example:

Select the	CodeList to use X
?	CL.IT.Activity [CL.IT.Activity] CL.IT.Parameter [CL.IT.Parameter] CL.IT.Parameter_description [CL.IT.Parameter_description] CL.IT.Treatment [CL.IT.Treatment] CL.IT.Parameter_NormalRange [CL.IT.Parameter_NormalRange]
	OK Cancel

e.g. leading to:

Fbringen I.ABTEST = spath(SubjEvenDual@fermOID=FO.DEFAULT)ItemGroupDual@ItemGroupOID='IG.DEFAULT)ItemDaal@ItemOID='IT Parameter][@Value='Therapper' or @Value='PT of gValue='PT of gVa	HepC	No mappings found for the	a coded value
Instrument Instrument Instrument Instrument Instrument Instrum	Fibrinogen	LB LBTESTCD	<pre>@Value=APTT or @Value=TNR!/@Value); if(SLATEST = FIbrinogen) (SLSLETESTCD = FIBRNO;) dshf(SLATEST = PT) { SLSLETESTCD = PT;) dshf(SLATEST = APTT) { SLSLETESTCD = FIPT; } dshf(SLATEST = TNR;) SLATESTCD = TNR; { } dsh { SLATESTCD = TNR; } dsh { } dst {</pre>
Instrument Instrument Instrument Instrument Instrument Instrument Instrument Instrument			
PT SLABTEST = xpath(StudyEventData FormData[@FormOID=FO.DEFAULT) ItemGroupData[@ItemGroupOID=IG.DEFAULT] ItemData[@ItemOID=TT.Parameter][@Value=Ftbrinogen' or @Value=PT or @Value=ITT or @Value=ITR]/@Value; iffSLAFTEST = FireInogen) (SLABTEST = FIFENDO;) elsifSLABTEST = FTFNO;) elsifSLABTEST = FTFNO;) elsifSLABTEST = PT) { SLABTESTCD = PT; } elsifSLABTEST = TNR) (SLABTESTCD = TNR; } elsif	INR	LB LBTESTCD	<pre>@Value=APTT or @Value=TNRY@Value); if(JLABTEST = Fibmogsth) { SL5_ISTESTCD = FIBANO; } } dstf(SLABTEST = PTT) { SL5_ISTESTCD = PTT; } dstf(SLABTEST = APTT) { SL5_ISTESTCD = VPTT; } dstf(SLABTEST = TNR) { SLABTESTCD = VNR; } dst { }</pre>
@Value=#PTT or @Value=TNRY@Value); iff(LABTEST = FWING); iff(LABTEST = FWING); } estif(LABTEST = FWING); } estif(LABTEST = FWING); } estif(LABTEST = FWING); } estif(LABTEST = TNR);	LabCoag	No mappings found for the	e oded value
	PT	LB LBTESTCD	<pre>@Vianc=2PTT or @Vianc=/TRR')@Vianc); if(JLABTEST = Fibmonger)) } BisIg(JLABTEST = PTT) { J.SLBIETSTCD = 'PTT } } bisIg(JLABTEST = 'aPTT) { J.SLBIETSTCD = 'APTT' } bisIg(JLABTEST - 'aPTT' } bisIg(JLABTEST - TNR') { J.SLABTESTCD = 'INR'; } bisIg {</pre>
			<< < > >> Save HTML

×

also here, having a "No mapping found for the coded item" does not necessarily mean that there should be, but one should at least check it.

Checking completeness on the SDTM side

Message

On the SDTM side, one can always see which variables are, according to the SDTMIG, are "required", "expected" or "permissible, by the color in the template or the study instance, when there is no mapping provided yet:

Domains (Iten	nGroups)										
Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	T
r v	STUDTID	DOMAIN	TV.VISITINUM	TV.VISIT	TV.VISITUY	TV.ARMCD	TV.ARM	TV.TVSTRL	TV.TVENKL		1
rs	STUDYID	DOMAIN	TS.TSSEQ	TS.TSGRPID	TS.TSPARMCD	TS.TSPARM	TS.TSVAL	TS.TSVALNF	TS.TSVALCD	TS.TSVCDREF	TS
D	STUDYID	DOMAIN	TD.TDORDER	TD.TDANCVAR	TD.TDSTOFF	TD.TDTGTPAI	TD.TDMINPAI	TD.TDMAXPAI	TD.TDNUMRPT		
00	STUDYID	DOMAIN	RDOMAIN	USUBJID	CO.COSEQ	CO.IDVAR	CO.IDVARVAL	CO.COREF	CO.COVAL	CO.COEVAL	C
BE	STUDYID	DOMAIN	USUBJID	SE.SESEQ	SE.ETCD	SE.ELEMENT	SE.SESTDTC	SE.SEENDTC	SE.TAETORD	SE.EPOCH	SE
SV	STUDYID	DOMAIN	USUBJID	SV.VISITNUM	SV.VISIT	SV.VISITDY	SV.SVSTDTC	SV.SVENDTC	SV.SVSTDY	SV.SVENDY	S١
CM	STUDYID	DOMAIN	USUBJID	CM.CMSEQ	CM.CMGRPID	CM.CMSPID	CM.CMTRT	CM.CMMODIFY	CM.CMDECOD	CM.CMCAT	CI
EC	STUDYID	DOMAIN	USUBJID	EC.ECSEQ	EC.ECGRPID	EC.ECREFID	EC.ECSPID	EC.ECLNKID	EC.ECLNKGRP	EC.ECTRT	EC
X	STUDYID	DOMAIN	USUBJID	EX.EXSEQ	EX.EXGRPID	EX.EXREFID	EX.EXSPID	EX.EXLNKID	EX.EXLNKGRP	EX.EXTRT	E)
۶R	STUDYID	DOMAIN	USUBJID	PR.PRSEQ	PR.PRGRPID	PR.PRSPID	PR.PRLNKID	PR.PRLNKGRP	PR.PRTRT	PR.PRDECOD	PF
SU	STUDYID	DOMAIN	USUBJID	SU.SUSEQ	SU.SUGRPID	SU.SUSPID	SU.SUTRT	SU.SUMODIFY	SU.SUDECOD	SU.SUCAT	SL
λE	STUDYID	DOMAIN	USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID	AE.AESPID	AE.AETERM	AE.AEMODIFY	AE.AELLT	AE
DE	STUDYID	DOMAIN	USUBJID	CE.CESEQ	CE.CEGRPID	CE.CEREFID	CE.CESPID	CE.CETERM	CE.CEDECOD	CE.CECAT	CE
DV VC	STUDYID	DOMAIN	USUBJID	DV.DVSEQ	DV.DVREFID	DV.DVSPID	DV.DVTERM	DV.DVDECOD	DV.DVCAT	DV.DVSCAT	D١
10	STUDYID	DOMAIN	USUBJID	HO.HOSEQ	HO.HOGRPID	HO.HOREFID	HO.HOSPID	HO.HOTERM	HO.HODECOD	HO.HOCAT	н
DS .	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DSDECOD	DS.DSCAT	D
ИН	STUDYID	DOMAIN	USUBJID	MH.MHSEQ	MH.MHGRPID	MH.MHREFID	MH.MHSPID	MH.MHTERM	MH.MHMODIFY	MH.MHDECOD	Mł
DA	STUDYID	DOMAIN	USUBJID	DA.DASEQ	DA.DAGRPID	DA.DAREFID	DA.DASPID	DA.DATESTCD	DA.DATEST	DA.DACAT	D/
DD	STUDYID	DOMAIN	USUBJID	DD.DDSEQ	DD.DDTESTCD	DD.DDTEST	DD.DDORRES	DD.DDSTRESC	DD.DDRESCAT	DD.DDEVAL	DI
EG	STUDYID	DOMAIN	USUBJID	EG.EGSEQ	EG.EGGRPID	EG.EGREFID	EG.EGSPID	EG.EGTESTCD	EG.EGTEST	EG.EGCAT	EC
E	STUDYID	DOMAIN	USUBJID	IE.IESEQ	IE.IESPID	IE.IETESTCD	IE.IETEST	IE.IECAT	IE.IESCAT	IE.IEORRES	E(
S	STUDYID	DOMAIN	USUBJID	IS.ISSEQ	IS.ISGRPID	IS.ISREFID	IS.ISSPID	IS.ISTESTCD	IS.ISTEST	IS.ISCAT	IS
_B	STUDYID	DOMAIN	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTESTCD	LB.LBTEST	LB.LBCAT	LE
ЛВ	STUDYID	DOMAIN	USUBJID	MB.MBSEQ	MB.MBGRPID	MB.MBREFID	MB.MBSPID	MB.MBTESTCD	MB.MBTEST	MB.MBCAT	ME
MS	STUDYID	DOMAIN	USUBJID	MS.MSSEQ	MS.MSGRPID	MS.MSREFID	MS.MSSPID	MS.MSTESTCD	MS.MSTEST	MS.MSCAT	M
AL	STUDYID	DOMAIN	USUBJID	MI.MISEQ	MI.MIGRPID	MI.MIREFID	MI.MISPID	MI.MITESTCD	MI.MITEST	MI.MITSTDTL	MI
 10	STUDYID	DOMAIN	USUBJID	MO.MOSEQ	MO.MOGRPID	MO.MOREFID	MO.MOSPID	MO.MOLNKID	MO.MOTESTCD	MO.MOTEST	M
PC	STUDYID	DOMAIN	USUBJID	PC.PCSEQ	PC.PCGRPID	PC.PCREFID	PC.PCSPID	PC.PCTESTCD	PC.PCTEST	PC.PCCAT	PC
- P	STUDYID	DOMAIN	USUBJID	PP.PPSEQ	PP.PPGRPID	PP.PPTESTCD	PP.PPTEST	PP.PPCAT	PP.PPSCAT	PP.PPORRES	PF
PE	STUDYID	DOMAIN	USUBJID	PE.PESEQ	PE.PEGRPID	PE.PESPID	PE.PETESTCD	PE.PETEST	PE.PEMODIFY	PE.PECAT	PE
25	STUDYID	DOMAIN	USUBJID	QS.QSSEQ	QS.QSGRPID	QS.QSSPID	QS.QSTESTCD	QS.QSTEST	QS.QSCAT	QS.QSSCAT	Q
RP	STUDYID	DOMAIN	USUBJID	RP.RPSEQ	RP.RPGRPID	RP.RPREFID	RP.RPSPID	RP.RPTESTCD	RP.RPTEST	RP.RPCAT	RF
SC SC	STUDYID	DOMAIN	USUBJID	SC.SCSEQ	SC.SCGRPID	SC.SCSPID	SC.SCTESTCD	SC.SCTEST	SC.SCCAT	SC.SCSCAT	
S	STUDYID	DOMAIN	USUBJID	SS.SSSEQ	SS.SSGRPID	SS.SSSPID	SS.SSTESTCD	SS.SSTEST	SS.SSCAT	SS.SSSCAT	SC SS
U	STUDYID	DOMAIN	USUBJID	TU.TUSEQ	TU.TUGRPID	TU.TUREFID	TU.TUSPID	TU.TULNKID	TU.TUTESTCD	TU.TUTEST	TL
TR	STUDYID	DOMAIN	USUBJID	TR.TRSEQ	TR.TRGRPID	TR.TRREFID	TR.TRSPID	TR.TRLNKID	TR.TRLNKGRP	TR.TRTESTCD	TF
RS	STUDYID	DOMAIN	USUBJID	RS.RSSEQ	RS.RSGRPID	RS.RSREFID	RS.RSSPID	RS.RSLNKID	RS.RSLNKGRP	RS.RSTESTCD	R
(S	STUDYID	DOMAIN	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VSCAT	VS.VSSCAT	VS
75 FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST	FA.FAOBJ	FA.FACAT	FA
A	STUDIND	DOMAIN	OSOBJID	FAFASEQ	FAFAGRPID	FA.FASPID	FAFATESTCD	FAFATEST	FA.FAUBJ	FALFAGAT	F/P

"Required" variables are colored red, "Expected" variables are colored blue, and "Permissible" variables are colored green.

So, one may think "as long as we don't see any "red" variables anymore in our study-specific instance (as these have been 'grayed out'), we are safe ...". Well, this is a minimum requirement ...

Of course, if one has source data that would need to go into one of the "expected" variables, and even in one of the "permissible" variables, one should provide mappings for these. And, even then, one may have data in the source that require to add standard variables for the SDTM class ("Findings", "Events", "Interventions"), that are not explicitly in the SDTMIG for that domain. I am thinking about e.g. "time points" (--TPT, --TPTNUM, --TPTREF, --RFTDTC) which are not always mentioned in the SDTMIG for "Findings" domains. And then there still are the famous "standard non-standard" variables, such as --CLSIG (Clinical Significance) and --REASOC (Reason why the intervention did not occur).

When applicable, one should also look into the "<u>CDISC Therapeutic Area Guidelines</u>" (TAUGs) for what variables should be included. These tend to mandate, recommend additional variables, or not to use, or use in a specific way, variables from the standard SDTMIG.

Conclusion

Achieving mapping completeness is not easy. Essentially, generating SDTM and SEND datasets is a "categorization", ETL-like exercise. Most of the information from the source will be used in the mappings, but not all of it. Some source data is used in different domains and variables (unfortunately, SDTM has a lot of data redundancy), and will then used in different mappings.

Fortunately, SDTM-ETL comes with a number of features and tools that make it easier (and more user-friendly) to check for mapping completeness.