SDTM-ETL 4.4 User Manual and Tutorial

Author: Jozef Aerts, XML4Pharma

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Handling multiple Codelists: CDISC Controlled Terminology Relationships

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Introduction

For a number of variables in SDTM, there are multiple codelists. Examples are EGSTRESC, and DSDECOD. Also in oncology studies, we may have to choose between different codelists for RSCAT, even having different versions of RECIST.

Usually, the one to be chosen will depend on the use case, or on the value of another variable, like for DSDECOD depending on the value of DSCAT.

These "relationships" have been made available in an electronic form by CDISC, for different versions of the standard, and are available in the form of a number of JSON files.

Multiple Codelists

Whether an SDTM variable is under controlled terminology can easily be found out by using the menu "View - SDTM CDISC Notes" (or using CTRL-H). For example, for LBTESTCD, we get:

i	Variable: LBTE STCD	•					
	CDISC Notes:						
	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "ALT", "LDH".						
	Core: Req						
	CDISC-CT information:						
->	Codelist C65047 (LBTE STCD - Laboratory Test Code):						
		-					
	Add CDISC Library information						
	View Document for:						
	SDTM Spec. v.1.7 SDTM-IG 3.3						
	OK						

showing that there is only one associated codelist for the variable LBTESTCD.

When is however more than one associated codelist (or better, the user will have to choose between different codelists, depending on the use case or the value of other variables), the "CT-relationships" file for the current SDTMIG version is read, and the information displayed. For example for EGSTRESC, using the menu "View - SDTM CDISC Notes" (CTRL-H), we get:

SDTM CDISC Note for Variable EG.EGSTRESC

Holtor monito					
Holler monito	ning (nestresc).				
Core: Exp					
CDISC-CT Rel	ations information:				
Following Cod generated):	eLists can be used (or a Val	lueList can be			
- C71150 (EGS Based on reg	STRESC - ECG Result): ular 10-second ECGs	-			
- C120522 (HESTRESC - Holter ECG Results): Based on Holter monitoring					
- C101834 (NO Valid when EC and collected CT. Sponsors values NORM practices.	RMABNM - Normal Abnorma TEST EQ "Interpretation" ar results reflect the values in may use this codelist or ext AL, ABNORMAL, etc. as per s	al Response): nd EGTESTCD EQ "INTP" the referenced CDISC tend EGSTRESC with sponsor data collection			
•		•			
	Add CDISC Library info	ormation			
View Docume	nt for:				
	SDTM Spec. v.1.7	SDTM-IG 3.3			
	ОК				

presenting 3 codelists for EGSTRESC.

It also states that we can either associate one of these 3 codelists, or that we can later generate "value lists" where we will have "where clauses" for determining which codelist is associated for which case (see the separate tutorial "Working with ValuesLists and the WhereClause in define.xml 2.0/2.1").

For DSDECOD, we get:

D	CONSENT OBTAINED", "RANDOMIZED". There are separate codelists used for DSDECOD where the choice depends on the value of DSCAT. Codelist "NCOMPLT" is used for disposition events and codelist "PROTMLST" is used for protocol milestones. The variable may be subject to controlled terminology for other events.	
	Core: Req	
	CDISC-CT Relations information:	
	Following CodeLists can be used (or a ValueList can be generated):	
	- C66727 (NCOMPLT - Completion/Reason for Non-Completion):	=
	- C114118 (PROTMLST - Protocol Milestone):	
	- C150811 (OTHEVENT - Other Disposition Event Response): This codelist is not referenced in SDTMIG v3.3 but is part of published CT.	
		-
	Add CDISC Library information	
	View Document for:	
	SDTM Spec. v.1.7 SDTM-IG 3.3	
	ОК	

Also presenting us 3 possibilities.

Assigning the codelist

There are now several possibilities for assigning the codelist in the case of multiple codelists.

The first is to "edit" the properties of the SDTM variable, using the menu "Edit - SDTM Variable Properties" (CTRL-E). For example, for EGSTRESC, this leads to:

Edit Properties for SDTM Variable EG.EGSTRESC

?	OID:	EG.EG STRE SC	
	New OID		Edit
	Name:	EGSTRESC	
	SASFieldName:	EGSTRESC	
	Data type:	text	
	Current Length:	80	
	New Length:		
	Current Significant Digits:		
	New Significant Digits:	-1	
	Current Role:	Result Qualifier	
	New Role	Result Qualifier	
	Current Role CodeList:		
	New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)	
	Current Origin/Source:	NONE DEFINED YET	
	Edit Origin/Source:		Edit
	Comment:		
	External document for comment		
	Current CodeList	CL.C71150.EGSTRESC	
	New CodeList:		Select CodeList
	Description:	Character Result/Finding in Std Format	
	current def:DisplayFormat:		
	New def:DisplayFormat:		
	current ValueList OID:	NO VALUELIST ASSIGNED	
	New ValueList OID	NO VALUELIST	
			OK Cancel

where the most probable value (codelist C71150 - ECG Result based on regular 10-second ECGs) is assigned. By clicking the checkbox "New CodeList" we can now select another, e.g. search for "Holter" and selecting the C120522 codelist:

CL.C120522.HE STRE	SC - Holter ECG Results (1	ext) 🚤 🔤								
CL.C120523.HETEST	CD - Holter ECG Test Code	e (text)								
CL.C120524.HETEST	- Holter ECG Test Name (1	text)								
CL.C103469.HAD \$01	CL.C103469.HADS01TC - Hospital Anxiety and Depression Scale Question									
 CL.C103468.HADS01TN - Hospital Anxiety and Depression Scale Question CL.C166188.HDCAB1TC - Huntington's Disease Cognitive Assessment Bat CL.C166187.HDCAB1TN - Huntington's Disease Cognitive Assessment Bat 										
								CL.C163393.HC \$017	C - Hypoglycemic Confide	nce Scale Questionnaire Te
								CL.C163392.HC \$017	N - Hypoglycemic Confide	nce Scale Questionnaire Te
CL.C120525.ISTEST	CL.C120525.ISTESTCD - Immunogenicity Specimen Assessments Test Co									
 CL.C120526.ISTEST - Immunogenicity Specimen Assessments Test Name CL.C189267.ISFTSDTL - Immunogenicity Specimen Test Details (text) CL.C113856.IVIS01TC - Impact of Visual Impairment Scale Questionnaire CL.C113855.IVIS01TN - Impact of Visual Impairment Scale Questionnaire 										
							CL.C170445.INTEGU	CD - Integumentary System	n Test Code (text)	
							CL.C170444.INTEGU	- Integumentary System T	est Name (text)	
									•	
Search										
Holter										
Search	Find Next	Find Previous								
	Show Details									
	OK Cancel									

After clicking "OK", the codelist is re-assigned:

Current Origin/Source:	NONE DEFINED YET	
Edit Origin/Source:		Edit
Comment:		
External document for comment		
Current CodeList	CL.C120522.HESTRESC - Holter ECG Results (text)	
✓ New CodeList:	Sel	lect CodeList
Description:	Character Result/Finding in Std Format	
current def:DisplayFormat:		

Important now is that in case we want to have a "value list" (ValueList) for the variable, i.e. the codelist to be used for EGSTRESC depends on something else, like the value of EGCAT, we do not assign a codelist on the variable level. To do so, for the codelist selection, select "No CodeList", which is at the bottom of the list:

 \times



In case we have no codelist assigned for EGSTRESC, and we start a mapping by drag-and-drop, or by a double-click on the SDTM cell, a dialog will pop up, presenting us the possibilities again:

CT-Relationships

?	Variable EGSTRESC currently has no associated codelist but the CDISC CT-relations suggests the following codelist to be used: C71150 (EGSTRESC - ECG Result) Based on regular 10-second ECGs Usage: SDTMIG v3.3
	C120522 (HE STRE SC - Holter ECG Results) O Based on Holter monitoring Usage: SDTMIG v3.3
	C101834 (NORMABNM - Normal Abnormal Response) Valid when EGTEST EQ "Interpretation" and EGTESTCD EQ "INTP" and collected results reflect the values in the referenced CDISC CT. Sponsors may use this codelist
	or extend EGSTRESC with values NORMAL, ABNORMAL, etc. Usage: SDTMIG v3.3
	or extend EGSTRESC with values NORMAL, ABNORMAL, etc. Usage: SDTMIG v3.3 Do not change or add a specific codelist right now. I will add a ValueList later when necessary.
	or extend EGSTRESC with values NORMAL, ABNORMAL, etc. Usage: SDTMIG v3.3 Do not change or add a specific codelist right now. I will add a ValueList later when necessary. Add a sticky note to remember me to add a ValueList

When we indeed want to assign a ValueList later, we select "Do not change or add a specific codelist now ...":

CT-Relationships

?	Va bu	riable EGSTRESC currently has no associated codelist t the CDISC CT-relations suggests the following codelist to be used: C71150 (EGSTRESC - ECG Result) Based on regular 10-second ECGs Usage: SDTMIG v3.3
		C120522 (HESTRESC - Holter ECG Results) O Based on Holter monitoring Usage: SDTMIG v3.3
		C101834 (NORMABNM - Normal Abnormal Response) Valid when EGTEST EQ "Interpretation" and EGTESTCD EQ "INTP" and collected results reflect the values in the referenced CDISC CT. Sponsors may use this codelist or extend EGSTRESC with values NORMAL, ABNORMAL, etc. Usage: SDTMIG v3.3
-	~	 Do not change or add a specific codelist right now. I will add a ValueList later when necessary.
		Add a sticky note to remember me to add a ValueList
		Do not show this dialog again for this variable

If we then also check the checkbox "Add a sticky note to remember me to add a ValueList", we see that, after closing the mapping, a "pin" is on the SDTM cell:

	~	
su(- 🛱 FG.EGSTRESC	EG.EGSTI

And when we then use the menu "Edit - Sticky Note for SDTM variable":

•	Edit	View	Navigate	Explore	Insert	Transform	Va	lidate	CDIS	C Library
0	Copy	/ Doma	in/Dataset			Ctrl-B	•	Dom	nains ((ItemGrou
	Past	te Doma	ain/Dataset			Ctrl-U		/ariab	le	Var
1	Remove Domain/Dataset					Ctrl-Delete		MOCO		CM CMS
1	Tran	spose	Domain/Dat	taset		Ctrl-T		DOSE	:	EX.EXDC
1	SDT	M Varia	ble Propert	ties		Ctrl-E		CSCAT	- Г	EC.ECPI
	SDT	M Dom:	ain Properti	68		Shift-E		REAS	SND	ML.MLD(
	CDT	M Codo	List	00		onne E		RPRES	SP	PR.PRO
	SUI	w code	LISU					hocc	UR	SU.SUS
	SDT	M Value	eList					PTCD		AE.AEHL
	SDT	M Value	eList Variab	le				FOCC	UR	CE.CES
								BDTC		DS.DSS
	Link	s to ext	ternal docu	ments				STDT	C	DV.DVEN
	defir	ie.xml (Global Varia	ables				pocc	UR	HO.HOS
	041-1		ALL COTMAN	(HSCA	Т	MH.MHP
	SUC	ky Note	TOF SDIM V	ariable				ORR	ESU	DA.DAS1
	Rem	ove Sti	cky Note fr	om SDTM	Add or E	dit a Sticky No	ote o	n a SD	TM Va	riable
	Trial	Design	Dataset					00		LO.LGB

The "sticky note" is visualized and can be edited:

?	You may still want to generate a ValueList as the variable has different codelists depending on the use case.
	The possible codelists are:
	- C71150: Based on regular 10-second ECGs
	- C120522: Based on Holter monitoring
	- C101834: Valid when EGTEST EQ "Interpretation" and EGTESTCD
	EQ "INTP" and collected results reflect the values
	in the referenced CDISC CT. Sponsors may use this codelist
	or extend EGSTRESC with values NORMAL, ABNORMAL, etc.
	OK Cancel

When starting the mapping for EGSTRESC, and a codelist is already associated to the variable, the same dialog will be shown, still allowing to change the choice, but when then selecting "Do not change or add ...", the already associated codelist will remain.

Similarly for DSDECOD, for which no initial codelist is present / assigned, when starting the mapping, the following dialog is displayed:

CT-Relat	ionships X	2
?	Variable DSDECOD currently has no associated codelist but the CDISC CT-relations suggests the following codelist to be used C66727 (NCOMPLT - Completion/Reason for Non-Completion) Usage: SDTMIG v3.3 Condition: DSCAT EQ "DISPOSITION EVENT"	:
	C114118 (PROTMLST - Protocol Milestone) Usage: SDTMIG v3.3 Condition: DSCAT EQ "PROTOCOL MILESTONE"	
	C150811 (OTHEVENT - Other Disposition Event Response) This codelist is not referenced in SDTMIG v3.3 but Usage: SDTMIG v3.3 Condition: DSCAT EQ "OTHER EVENT"	
	 Do not change or add a specific codelist right now. I will add a ValueList later when necessary. 	
	Add a sticky note to remember me to add a ValueList	_
	Do not show this dialog again for this variable	

Creating ValueLists

Now, in the case of DS, which contains information about a mixture of events¹, we will typically want to use a ValueList, in which we assign the codelist for DSDECOD depending on the value of DSCAT, as already indicated in the dialog.

We can do this in a semi-automated way by using the menu "Insert - Generate ValueList from Existing CodeList":

	Insert Transform Validate CDISC Library Options About										
1	Global Variables from ODM into define.xml										
	MeasurementUnit definitions from ODM into define.xml										
	All CodeList definitions from ODM into define.xml										
c	Selected CodeList definitions from ODM into define.xml	EC.E									
1	CodeList definitions from File into define.xml	ML.M									
2	ValueLists for CDISC CodeTables from File into define.xml	PR.P									
k	Create new SDTM CodeList from existing CodeList	AE.AE									
k	Create Enumerated CodeList from CodeListItem CodeList	CE.C									
1	Create new SDTM Sponsor-defined CodeList	DS.D									
π	Create new SDTM CodeList from MeasurementUnits	HO H									
f	Create new ValueList from existing CodeList	MH.M									
f	Create mapping formula Ctrl-M	DA.D									

and select the codelist for "DSCAT" as the base of the ValueList:

¹ I often call DS "the garbage can of events" ...

Select CodeList to convert to a ValueList

CL.C74558.DSCA - Category of Disposition Event CL.C115304.FTCAT - Category of Functional Test CL.C66797.IECAT - Category of Inclusion/Exclusion CL.C124298.ONCRSCAT - Category of Oncology Response Assessment CL.C100129.QSCAT - Category of Questionnaire CL.C150812.CDFATSCD - CDAD Findings About Test Code CL.C124678.CHIVC1TC - CDC Classification System for HIV-Infected Adults CL.C124677.CHIVC1TN - CDC Classification System for HIV-Infected Adults CL.C160925.CTAUGRS - CDISC Therapeutic Area User Guide Response CL.C181173.CPTESTCD - Cell Phenotyping Test Code CL.C181172.CELSTATE - Cell Phenotyping Test Name CL.C120988.CPS01TC - Child-Pugh Classification Clinical Classification Te CL.C120988.CPS01TN - Child-Pugh Classification Clinical Classification Te CL.C154447.CDRS1TC - Children's Depression Rating Scale, Revised Clinit Search DSCAT Show Details V Create simple 'WhereClause' automatically											
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CL.C120989.CPS01TC - Child-Pugh Classification Clinical Classification Te CL.C120988.CPS01TN - Child-Pugh Classification Clinical Classification Te CL.C154447.CDRS1TC - Children's Depression Rating Scale, Revised Clinic CL.C154447.CDRS1TC - Children's Depression Rating Scale, Revised Clinic CL.C154447.CDRS1TC - Children's Depression Rating Scale, Revised Clinic Search DSCAT Search Find Next Find Previous Show Details Create simple 'WhereClause' automatically OK Cancel	CL.C181172.CEL STA	TE - Cell State Response									
CL.C120988.CP S01TN - Child-Pugh Classification Clinical Classification Te CL.C154447.CDR S1TC - Children's Depression Rating Scale, Revised Clinic Search DSCAT Search Find Next Find Previous Show Details Create simple 'WhereClause' automatically OK Cancel	CL.C120989.CP \$017	C - Child-Pugh Classificat	on Clinical Classification Te								
CL.C154447.CDRS1TC - Children's Depression Rating Scale, Revised Clinic	CL.C120988.CP \$017	N - Child-Pugh Classificat	on Clinical Classification Te								
Search DSCAT Search Find Next Find Previous Create simple 'WhereClause' automatically OK Cancel	CL.C154447.CDR\$1	FC - Children's Depression	Rating Scale, Revised Clinic								
Search DSCAT Search Find Next Find Previous Show Details Create simple 'WhereClause' automatically OK Cancel	•		•								
DSCAT Search Find Next Find Previous Show Details Show Details Create simple 'WhereClause' automatically OK Cancel	Search										
Search Find Next Find Previous Show Details Create simple 'WhereClause' automatically OK Cancel	DSCAT										
Show Details Create simple 'WhereClause' automatically OK Cancel	Search	Find Next	Find Previous								
Create simple 'WhereClause' automatically		Show Details									
OK Cancel											
OK Cancel	Create simple When	reclause' automatically									
		OK Cancel									

 \times

We can also already have the system generate the "WhereClause" automatically by checking the checkbox "Create simple WhereClause automatically". After clicking OK:

🍰 Crea	Create new SDTM ValueList from existing CodeList												
?	?												
	CL.C74558.DSCAT - Category	of Disposition Event											
	New OID:							VL.CL.C74558.DS	CAT				
													1
	OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display	Method	CodeList	WhereClause	
	IT.DISPOSITION_EVENT	DISPOSITION EVENT						DISPOSITION EVENT				WC.IT.DISPOSITION_EVENT	
	IT.OTHER EVENT	OTHER EVENT						OTHER EVENT				WC.IT.OTHER EVENT	
	IT.PROTOCOL_MILESTONE	PROTOCOL MILESTONE						PROTOCOL MILESTONE				WC.IT.PROTOCOL_MILESTONE	1

When clicking on one of the "WhereClause" cells, we can edit or visualize the Where-clause:

Sesigning/Updating WhereClause for Item: IT.DISPOSITION_EVENT

OID:	WC.I	T.DISPOSITION_EVENT	
Comment:			External document for comment
		Show 'Where' clause	
		Number of RangeChecks: 1 ×	
			-
	Comparator: EQ 💌 Item OID:	DS.DSCAT DS.DSCAT DS.DSSCAT DS.EPOCH DS.DSDTC DS.DSSTDTC DS.DSSTDY DV.DVSEQ DV.DVREFID DV.DVREFID DV.DVSPID DV.DVTERM	CheckValue: DISPOSITION EVEN

We can add a comment and/or a link to an external document (very uncommon in this case), and getting the human-understandable phrase by clicking the button "Show 'Where' Clause):

🛓 Desi	gning/Updating WhereClause for	Item: IT.DISPOSITION_EVENT	\times
?	OID:	WC.IT.DISPOSITION_EVENT	
_	Comment:	External document for comment	
		Show 'Where' clause	
		Number of RangeChecks: $1 \frac{1}{-}$	
		Where-Clause Expression X	-
		i where DSCAT EQ 'DISPOSITION EVENT'	
		OK	
		DS.DSCAT	
		DS.EPOCH	

Now going back to the dialog showing the ValueList editor, we can start adding additional information, like the datatype for the 3 use cases:

Х

CL.C74558.DSCAT - Category	of Disposition Event				
New OID:					
OID	Name	Data Typ	е	Length	Sig
IT.DISPOSITION_EVENT	DISPOSITION EVENT		•		
IT.OTHER_EVENT	OTHER EVENT	text			
IT.PROTOCOL_MILESTONE	PROTOCOL MILESTONE	integer			
		float			
		datetime	=		
		dato			
		timo			
		unie			
		partialDat			
		partialTim	•		

But most importantly, the codelist for each of the use cases. So for the case of "Disposition Event", we can set the associated codelist by clicking in the corresponding cell:

CL.C74558.DSCAT - Category of Disposition Event										
New OID: VLCLC74558.DSCAT										
1						1	1 1			
Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display	Method	CodeList	WhereClaus
DISPOSITION EVENT						DISPOSITION EVENT				WC.IT.DISPOSITION_EVI
OTHER EVENT						OTHER EVENT				C.IT.OTHER_EVENT
PROTOCOL MILESTONE						PROTOCOL MILESTONE				WC.IT.PROTOCOL_MILE
	of Disposition Event Name DISPOSITION EVENT OTHER EVENT PROTOCOL MILESTONE	of Disposition Event Name Data Type DISPOSITION EVENT OTHER EVENT OTHER EVENT PROTOCOL MILESTONE	of Disposition Event Name Data Type Length DISPOSITION EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event Name Data Type Length Sign.Digits DISPOSITION EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event Name Data Type Length Sign.Digits Origin DISPOSITION EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event Name Data Type Length Sign.Digits Origin Comment DISPOSITION EVENT OTHER EVENT OTHER EVENT PROTOCOL MILESTONE OTHER EVENT OTHER EVENT	of Disposition Event VL.CL.C74558 DS Name Data Type Length Sign.Digits Origin Comment Description DISPOSITION EVENT OTHER EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event VLCLC74558 DSCAT Name Data Type Length Sign.Digits Origin Comment Description def.Display DISPOSITION EVENT OTHER EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event VL_CLC74558_DSCAT Name Data Type Length Sign.Digits Origin Comment Description def.Display Method DISPOSITION EVENT DISPOSITION EVENT OTHER EVENT DISPOSITION EVENT Method OTHER EVENT OTHER EVENT OTHER EVENT PROTOCOL MILESTONE PROTOCOL MILESTONE	of Disposition Event VL_CL_C74558 DSCAT Name Data Type Length Sign.Digits Origin Comment Description def.Display Method CodeList DISPOSITION EVENT DISPOSITION EVENT

Leading to a "codelist selector":

Select a Co	odeList		×							
?	CL.C66727.NCOMPL	T - Completion/Reason fo	r Non-Completion							
	CL.C90018.C STATE	Consciousness State								
	CL.C101838.CCRCL	SCD - Consensus Cardiac	Classification System Test							
 CL.C101837.CCRCLS - Consensus Cardiac Classification System Test Nar CL.C102575.CCINVTYP - Contact Case Investigation Contact Type CL.C127257.CONROL - Contact Role for Clinical Study CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function 										
 CL.C102575.CCINVTYP - Contact Case Investigation Contact Type CL.C127257.CONROL - Contact Role for Clinical Study CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function 										
	CL.C127257.CONROL - Contact Role for Clinical Study									
	CL.C66785.TCNTRL - Control Type Response									
	CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function									
	CL.C150765.COWAT	1TN - Controlled Oral Wo	rd Association Test Function							
	CL.C122007.CPFATS	CD - COPD Findings Abou	it Test Code							
	CL.C122006.CPFATS	- COPD Findings About T	est Name							
	CL.C101843.CADPR	SN - Coronary Artery Dise	ase Presentation							
	Search									
	 CL.C66727.NCOMPLT - Completion/Reason for Non-Completion CL.C90018.CSTATE - Consciousness State CL.C101838.CCRCLSCD - Consensus Cardiac Classification System Test (CL.C101837.CCRCLS - Consensus Cardiac Classification System Test Nar CL.C102575.CCINVTYP - Contact Case Investigation Contact Type CL.C127257.CONROL - Contact Role for Clinical Study CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function CL.C122007.CPFATSCD - COPD Findings About Test Code CL.C101843.CADPRSN - Coronary Artery Disease Presentation Search completion Search Find Next Find Previous Show Details OK Cancel CL 									
CL.C101837.CCRCLS - Consensus Cardiac Classification System Test Nar CL.C102575.CCINVTYP - Contact Case Investigation Contact Type CL.C127257.CONROL - Contact Role for Clinical Study CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function CL.C122007.CPFATSCD - COPD Findings About Test Code CL.C122006.CPFATS - COPD Findings About Test Name CL.C101843.CADPRSN - Coronary Artery Disease Presentation Search Completion Find Next Find Previous										
CL.C101838.CCRCLSCD - Consensus Cardiac Classification System Test CL.C101837.CCRCLS - Consensus Cardiac Classification System Test Nar CL.C102575.CCINVTYP - Contact Case Investigation Contact Type CL.C127257.CONROL - Contact Role for Clinical Study CL.C66785.TCNTRL - Control Type Response CL.C150766.COWAT1TC - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function CL.C150765.COWAT1TN - Controlled Oral Word Association Test Function CL.C122007.CPFATSCD - COPD Findings About Test Code CL.C122006.CPFATS - COPD Findings About Test Name CL.C101843.CADPRSN - Coronary Artery Disease Presentation Search Completion Search Find Next Find Previous										
		OK Cancel								

Where we select the codelist "Completion/Reason for Non-Completion". We can show the details of the codelist by clicking "Show Details" leading to:

Select a Co	odeList				×			
?	CL.C66727	<u> </u>						
	CL CodeLis	t: Completi	on/Reason for Non-Comp	etion (OID: CL.C66727.NCOMF	чцт) X			
		ADVERS APPROV COMPLE DEATH [DISEASE FAILURE	E EVENT [C41331] /ED DRUG AVAILABLE FO ETED [C25250] C28554] E RELAPSE [C38155] TO MEET CONTINUATION	R INDICATION [C172573]				
		LACK OF EFFICACY [C48226] LOGISTICAL PROBLEM [C176343] LOST TO FOLLOW-UP [C48227]						
			OK					
	Search							
	Searc	h	Find Next	Find Previous				
			Show Details					

And after clicking "OK" twice, we see that the codelist has been assigned for the case of "disposition event":

Method	CodeList	WhereClause	
(CL.C66727.NCOMPLT	WC.IT.DISPOSITION_EVENT	
		WC.IT.OTHER_EVENT	
		WC.IT.PROTOCOL_MILESTONE	

We can then do the same for the cases of "Other Event" and "Protocol Milestone", leading to e.g.:

🛓 Create	Create new SDTM ValueList from existing CodeList											
?	?											
C	CL.C74558.DSCAT - Category of Disposition Event											
N	New OID: VLCLC74558 DSCAT											
_		-										
	OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display	Method	CodeList	WhereClause
п	DISPOSITION_EVENT	DISPOSITION EVENT	text	20				DISPOSITION EVENT			CL.C66727.NCOMPLT	WC.IT.DISPOSITION_EVENT
п	LOTHER_EVENT	OTHER EVENT	text	20				OTHER EVENT			CL.C150811.OTHEVENT	WC.IT.OTHER_EVENT
1	PROTOCOL_MILESTONE	PROTOCOL MILESTONE	text	20				PROTOCOL MILESTONE			CL.C114118.PROTMLST	WC.IT.PROTOCOL_MILESTONE

Remark that we just assign a "dummy" value for the maximal length for now, as we do not know yet what the values will be. This is essentially only needed because of the antique SAS Transport 5 format, and irrelevant when using a modern submission format like <u>CDISC Dataset-JSON</u> which will probably the FDA format of choice soon.

We still then need to assign this ValueList (with identifier VL.CL.C74558) to DSDECOD. To do so, select the DSDECOD cell in the SDTM table, and use the menu "Edit - SDTM Variable Properties" (CTRL-E):

Edit Droportion for SDTM Variable DS DSDECOD

Jei	ties for sprivi variable bs.bsbecob		
0	DID:	DS.DSDECOD	
	New OID		Edit
1	Name:	DSDECOD	
1	SA SFieldName:	DSDECOD	
1	Data type:	text	
(Current Length:	80	
	New Length:		
(Current Significant Digits:		
	New Significant Digits:	-1	
(Current Role:	Synonym Qualifier	
	New Role	Synonym Qualifier	
(Current Role CodeList:		
	New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)	
(Current Origin/Source:	NONE DEFINED YET	
	Edit Origin/Source:		Edit
0	Comment:		
[External document for comment		
Ì	Current CodeList	NO CODELIST ASSIGNED	
	New CodeList:		Select CodeList
1	Description:	Standardized Disposition Term	
•	current def:DisplayFormat:		
	New def:DisplayFormat:		
-	current ValueList OID:	NO VALUELIST ASSIGNED	
	New ValueList OID	VL.CL.C74558.DSCAT	
			UN Callee

and check the checkbox "New ValueList OID", and then select the one we just created:

NO CODELIST ASSIGNED
Standardized Disposition Term
NO VALUELIST ASSIGNED
VL.CL.C74558.DSCAT
VL.CL.C74558.DSCAT
NO VALUELIST

When then displaying the define.xml in the browser (using View - View define.xml in Browser), we e.g. get:

DSSPIDImage: Sponsor-Defined IdentifiertextIdentifier80DSTERMReported Term for the Disposition EventtextTopic80DSDECOD VLMStandardized Disposition TermtextSynonym80DSDECOD VLMDSSOETTON EVENTtextSynonym80DSDECOD VLMDISPOSITION EVENTtextSynonym80DSCAT = "OTHERDISPOSITION EVENTtextSundardized Disposition Ferm20DSCAT = "OTHEROTHER EVENTtextACompletion/Reason for Non-Completion (42 Terms)DSCAT = "OTHEROTHER EVENTtextLext20Other Disposition Event Response "FINAL CONTACT" "SITE TRANSFER" "WITHORAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"DSCAT = "PROTOCOLPROTOCOL MILESTONEtextCategory for Disposition EventtextGrouping Qualifier80Category of Disposition Event "DISPOSITION EVENT" "DISPOSITION EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "OTHER EVENT" "PROTOCOL MILESTONE"				1			
DSTERMReported Term for the Disposition EventtextTopic80DSDECOD VLMStandardized Disposition TermtextSynonym Qualifier80DSDECOD VLMDSCAT = "DISPOSITION EVENT"DISPOSITION EVENTtextSynonym Qualifier80DSCAT = "DISPOSITION EVENT"DISPOSITION EVENTtextSynonym Qualifier80DSCAT = "OTHER EVENT"DTHER EVENTtextImage: Sinon Sinon Event Response • "FINAL CONTACT" • "SITE TRANSFER" • "TREATMENT UNBLINDED" • "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"DSCAT = "PROTOCOL MILESTONE"PROTOCOL MILESTONEtextImage: Sinon Sinon Event Response • "FINAL CONTACT" • "SITE TRANSFER" • "TREATMENT UNBLINDED" • "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"DSCAT = "PROTOCOL MILESTONE"PROTOCOL MILESTONEtextGrouping Qualifier80Category of Disposition Event • "DISPOSITION EVENT" • "OTHER EVENT" • "PROTOCOL MILESTONE"	DSSPID		Sponsor-Defined Identifier	text	Identifier	80	
DSDECOD VIMStandardized Disposition TermtextSynonym Qualifier80DSCAT = "DISPOSITION EVENT"DISPOSITION EVENTtextImage: Completion/Reason for Non- 	DSTERM		Reported Term for the Disposition Event	text	Торіс	80	
DSCAT = "DISPOSITION EVENT"DISPOSITION EVENTtext20Completion/Reason for Non- Completion [42 Terms]DSCAT = "OTHER 	DSDECOD VLM		Standardized Disposition Term	text	Synonym Qualifier	80	
DSCAT = "OTHER EVENT"OTHER EVENTtextLext20Other Disposition Event Response • "FINAL CONTACT" • "SITE TRANSFER" • "TREATMENT UNBLINDED" • "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"DSCAT = "PROTOCOL 		DSCAT = "DISPOSITION EVENT"	DISPOSITION EVENT	text		20	Completion/Reason for Non- Completion [42 Terms]
DSCAT "PROTOCOL MILESTONE" PROTOCOL MILESTONE text 20 Protocol Milestone [11 Terms] DSCAT Category for Disposition Event text Grouping Qualifier 80 Category of Disposition Event • "DISPOSITION EVENT" • "OTHER EVENT" • "PROTOCOL MILESTONE"		<u>DSCAT</u> = "OTHER EVENT"	OTHER EVENT	text		20	Other Disposition Event Response "FINAL CONTACT" "SITE TRANSFER" "TREATMENT UNBLINDED" "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"
DSCAT Category for Disposition text Grouping Qualifier 80 Category of Disposition Event "DISPOSITION EVENT" "OTHER EVENT" "PROTOCOL MILESTONE"		DSCAT = "PROTOCOL MILESTONE"	PROTOCOL MILESTONE	text		20	Protocol Milestone [11 Terms]
	DSCAT		Category for Disposition Event	text	Grouping Qualifier	80	Category of Disposition Event • "DISPOSITION EVENT" • "OTHER EVENT" • "PROTOCOL MILESTONE"

the second column containing the "Where-Clause" and the column on the right, containing the associated codelist with the terms (the latter when the list is not too long). In this column, clicking on "Protocol Milestone [11 Terms] then jumps to the full codelist:

Protocol Milestone [C114118] [CDISC/NCI SDTM 2023-09-29]

Permitted Value (Code)
DECLINED TO CONTINUE INTO NEXT TRIAL ELEMENT [C186210]
DECLINED TO CONTINUE INTO SURVIVAL FOLLOW-UP [C176358]
ELIGIBILITY CRITERIA MET [C132447]
ELIGIBILITY CRITERIA NOT MET [C164344]
ENTERED INTO TRIAL [C161417]
INFORMED ASSENT OBTAINED [C161418]
INFORMED CONSENT OBTAINED [C16735]
OPTED TO CONTINUE INTO NEXT TRIAL ELEMENT [C186211]
OPTED TO CONTINUE INTO SURVIVAL FOLLOW-UP [C176357]
RANDOMIZED [C114209]
RE-RANDOMIZED [C186212]

In some cases, one will still want to edit or shorten the codelist (e.g. as not all protocol milestones are applicable), using the menu "Edit - SDTM CodeList", or generate a subset (keeping the original one as a 'backup'), or even extend it, using the menu "Insert - Create new SDTM CodeList from existing CodeList", but for DSDECOD, one will usually not do so.

Generating such a valuelist may sound like a lot of work, but once you know how to do this ("it's easy if you know how"), it will take you a few minutes only.

Also remember that you will often use the define.xml with the mappings of one study as a template define.xml for another study. In such a case, you will often not need to go to the above procedure again.

Some of our customers have reported 80% and more "reuse" of the mappings in the case of similar

studies in this way.

Pre-defined ValueLists

CDISC has published a number of "<u>code tables</u>", unfortunately (but typical for CDISC) as Excel files. We have transformed these into Define-XML valuelists, which can be immediately imported into SDTM-ETL. These can then be used when wanting to assign a ValueList, e.g. when there is more than one associated codelists for an SDTM variable.

To load such a pre-defined ValueList, use the menu "Insert - ValueLists for CDISC Code Tables from File into define.xml":

Insert Transform Validate CDISC Library Options A	bout						
Global Variables from ODM into define.xml							
MeasurementUnit definitions from ODM into define.xml			Variable	Variable	Variable	Variable	V
All CodeList definitions from ODM into define.xml				AG.AGOTTI I			
Selected Codel ist definitions from ODM into define yml		CM.CMSTRIPT	CM.CMSTIPT	CM.CMENRIPI	CM.CMENTPT		
Selected CodeList definitions from ODM into define.xim	-		EC ECDUR	EC ECTRT		ECEC	
CodeList definitions from File into define.xml		-	EC.ECENDT	EC.ECDUR	EG.EGTPT	EC.ECTPTINOM	EC.EC
ValueLists for CDISC CodeTables from File into define.xml				PR PRELTM	PR PRTPTREE	PR PRRETDTC	PR PR
Create new SDTM CodeList from existing CodeList							
Create Enumerated CodeList from CodeListItem CodeList	eL	ists, WhereClaus	es, CodeLists for C	DISC CodeTables	from file into defin	e.xml	
Create new SDTM Sponsor-defined CodeList							
Create new SDTM CodeList from MeasurementUnits		-					
Create new ValueList from existing CodeList							
Create mapping formula	Ctrl-M	_					
Sponsor defined SDTM Domain	CHL D						

A list of available files will then be displayed:

🎒 Open		×		
Look In:	CodeTables_ValueLists			
temp_Code	eTables	ValueList_CodeTable_RP.xml		
ValueList_	CodeTable_CV.xml	ValueList_Codetable_RS.xml		
ValueList_	CodeTable_DD.xml	ValueList_Codetable_R\$_iRANO.x		
ValueList_	CodeTable_GF.xml	ValueList_Codetable_RS_iRECIST.		
ValueList_	Codetable_Gl.xml	ValueList_Codetable_RS_LUGANO		
ValueList_	CodeTable_MK.xml	ValueList_Codetable_RS_RAJKUM		
•		•		
File <u>N</u> ame:	ValueList_CodeTable_CV.xml			
Files of <u>Type</u> :	All Files	-		
		Open Cancel		

When one clicks on a file name, information about what the file is about is displayed. For example for "ValueList_CodeTable_CV":

	🛓 Open								ST PID
	Look <u>I</u> n:		CodeTables_V	alueLists	•	a :			SPI RE
ON ON	📑 temp	Code	eTables		ValueList_C	odeTable_	RP.xml		PIE
ON	🗋 Value	List_	CodeTable_C	V.xml	ValueList_C	odetable_	RS.xml	:V	SP
NO	N Value	List	CodeTable D	D.xml	NalueList C	odetable	RS iRANG	D.x	SP
Cont	ents descri	ption						×	N
ĺ	Value	eList1	for the FASTR	ESC variable for t	he FACE domain	for Cardio	vasculars	studies	D U U D M
	File <u>N</u> ame	:	ValueList_Co	deTable_CV.xml					-E: PII
	Files of <u>T</u>	/pe:	All Files						TE
						Open	Cancel	S S	TE TE:
0	INI	LICI		TO TOPEO				TO TO	0

So, this one is for FASTRESC for FACE (Findings about Clinical Events), for cardiovascular studies. Just for the exercise, let us create an FACE instance. We can do so by drag-and-drop from the "FA" row from the template, after which a dialog is displayed:

FA datas	et ×
?	Do you want to create a generic FA datasets or a domain-specific FA dataset?
	GENERIC FA : Findings About Events or Interventions
	FAAG : Finding About Procedure Agents
	FACM : Finding About Concomitant/Prior Medications
	FAEX : Finding About Exposure
	FAEC : Finding About Exposure as Collected
	FAML : Finding About Meal Data
	FAPR : Finding About Procedures
	FASU : Finding About Substance Use
	FAAE : Finding About Adverse Events
	FACE : Finding About Clinical Events
	FADS : Finding About Disposition
	FADV : Finding About Protocol Deviations
	FAHO : Finding About Healthcare Encounters
	FAMH : Finding About Medical History
	OK Cancel

And select "FACE: Findings About Clinical Events".

The system then asks us what codelist we want to assign to FATESTCD. If we hover the mouse over "Cardiovascular Findings About Test Code", we get more details:



If we then select "Cardiovascular Findings About Test Code", we first get some advice about choosing a suitable structure for the dataset, and the "study-specific FACE instance" is created as a new row at the bottom:

		0100110							
	β TI	STUDYID	DOMAIN	TI.IETESTCD	TIJETEST	TI.IECAT	TI.IESCAT	TI.TIRL	TI.TIVERS
	TS	STUDYID	DOMAIN	TS.TSSEQ	TS.TSGRPID	TS.TSPARMCD	TS.TSPARM	TS.TSVAL	TS.TSVALNF
	RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID	
	SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	SUPPQUAL.QN	SUPPQUAL.QL	SUPPQUAL.QVAL
	RELSUB	STUDYID	USUBJID	RELSUB.POOLID	RELSUB.RSUB	RELSUB.SREL			
	01	STUDYID	DOMAIN	OI.NHOID	OI.OISEQ	OI.OIPARMCD	OI.OIPARM	OI.OIVAL	
	CES:FACE	STUDYID	DOMAIN	USUBJID	FACE.FASEQ	FACE.FAGRPID	FACE.FASPID	FACE.FATESTCD	FACE.FATEST

If we ask for the properties of FATESTCD (using the menu "Edit - SDTM Variable Properties), we see that the codelist "CVFATSCD" has been assigned to FATESTCD:

Edit Properties for SDTM Variable FACE.FATESTCD

?	OID:	FACE.FATESTCD
	New OID	Edit
	Name:	FATESTCD
	SASFieldName:	FATESTCD
	Data type:	text
	Current Length:	8
	New Length:	
	Current Significant Digits:	
	New Significant Digits:	-1
	Current Role:	Торіс
	New Role	
	Current Role CodeList:	
	New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)
	Current Origin/Source:	NONE DEFINED YET
	Edit Origin/Source:	Edit
	Comment:	
	External document for comment	
	Current CodeList	CL.C119015.CVFATSCD
	New CodeList:	Select CodeList
	Description:	Findings About Test Short Name
	current def:DisplayFormat:	
	New def:DisplayFormat:	
	current ValueList OID:	NO VALUELIST ASSIGNED
	New ValueList OID	NO VALUELIST
		OK Cancel

However, no codelist nor valuelist has yet been assigned to FASTRESC ...

Edit Properties for SDTM Variable FACE.FASTRESC

?	OID:	FACE.FASTRESC		
	New OID			Edit
	Name:	FASTRESC		
	SASFieldName:	FASTRESC		
	Data type:	text		
	Current Length:	80		
	New Length:			
	Current Significant Digits:			
	New Significant Digits:	-1		
	Current Role:	Result Qualifier		
	New Role	Result Qualifier		
	Current Role CodeList:			
	New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)		
	Current Origin/Source:	NONE DEFINED YET		
	Edit Origin/Source:			Edit
	Comment:			
	External document for comment			
	Current CodeList	NO CODELIST ASSIGNED		
	New CodeList:			Select CodeList
	Description:	Character Result/Finding in Std Format		
	current def:DisplayFormat:			
	New def:DisplayFormat:			
	current ValueList OID:	NO VALUELIST ASSIGNED		
	New ValueList OID	NO VALUELIST		
			OK Cancel	

We don't however want to assign a codelist to FASTRESC however, but a valuelist, as the properties of FASTRESC will depend on the value of FATESTCD.

We can now import the ValueList (generated from the CDISC code tables) that we need by using the menu "Insert - ValueLists for CDISC Code Tables from File into define.xml", and select the "CV" one:

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E.IESE B.ISSE B.LBS Look In:	CodeTables	_ValueLists		• 🖬 🔒 🖁	
IS.NH	p_CodeTables		🗋 ValueList	_CodeTable_RP.xn	
4I.MISE 🗋 Valu	eList_CodeTable	_CV.xml	🗋 ValueList	_Codetable_RS.xm	II EST
	eList CodeTable	DD.xml	ValueList	Codetable RS iR	ANO.x TES
IK Contents desc	ription				× ,
Valu Valu	ieList for the FAS	TRESC variable fo	or the FACE doma	in for Cardiovascul	ar studies
IR I					K
File Nam	e: ValueList_	CodeTable_CV.xr	nl		3041
E.PE: Files of	Type: All Files				
1.F13 28.QS				Open Car	CAT
(S.RS				Cul	

After selecting and clicking "OK" and "Open", the system will propose us to edit the imported ValueList:

SEQ E(S	elected	ValueLists to be	MO.MOREFID edited	MO.MOSPID	MO.MOLNKID	×	DV
通知活動	?	VL.FA.FAS	TRESC			▲ 	
)E SE JE			ОК	Cancel			re Uf PC
EO	P	P PPC PPID	PP PPTESTCD	PP PPTEST	PP PPCAT	PP	PP

This is a good idea, as we may still want or need to make decisions:

VLFAFASTRESC											
OID	Name	Data Type	Length	Sign.Dig	Origin	Comment	Description	def.Display	Method	CodeList	Where
T.CVFARS.C118936.ACMITYPE	Item Definition for CVFARS for CVTESTCD = ACMITYPE	text	29				Item Definition for CVFARS for the case that CV			CL.CVFARS.C118936.ACMITYPE	WC.CV
T.CVFARS.C119229.CATMTHID	Item Definition for CVFARS for CVTESTCD = CATMTHID	text					Item Definition for CVFARS for the case that CV			CL.CVFARS.C119229.CATMTHID	WC.C
CVFARS.C119231.HETYPE	Item Definition for CVFARS for CVTESTCD = HETYPE	text	29				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119231.HETYPE	wc.c
CVFARS.C119232.HFLBFNW	Item Definition for CVFARS for CVTESTCD = HFLBFNW	text	49				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119232.HFLBFNW	WC.C
CVFARS.C119234.HFTHERIN	Item Definition for CVFARS for CVTESTCD = HFTHERIN	text	35				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119234.HFTHERIN	WC.C
CVFARS.C119236.ISCETYP	Item Definition for CVFARS for CVTESTCD = ISCETYP	text	30				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119236.ISCETYP	WC.C
CVFARS.C123443.NINVIMGC	Item Definition for CVFARS for CVTESTCD = NINVIMGC	text	36				Item Definition for CVFARS for the case that CV			CL.CVFARS.C123443.NINVIMGC	WC.C
CVFARS.C119238.NWSYMP	Item Definition for CVFARS for CVTESTCD = NWSYMP	text	28				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119238.NWSYMP	WC.C
CVFARS.C119239.PCIAAC	Item Definition for CVFARS for CVTESTCD = PCIAAC	text	30				Item Definition for CVFARS for the case that CV			CL.CVFARS.C119239.PCIAAC	WC.C
CVEARS C123424 STCTIMNG	Item Definition for CVEARS for CVTESTCD = STCTIMNG	text	30				Item Definition for CVEARS for the case that CV			CL CVEARS C123424 STCTIMNG	WCC
CVEADE C110E70 STDOKTVD	Itom Definition for CVEADS for CVTESTCD - STROKTVP	tout	40				the set of			CL CVEARS C119579 STROKTVP	WC C
		IGN	19				item Delinition for CVPARS for the case that CV				inc.
LUT MAGU I BUT BSTRUKTT		(resu	19				item Delimition for CYTAKS for the case that CV_				
		(rex	19				item Delimition for CYTAKS for the case that CV				
Retrieve Mota	Jam Damman of the rest of the concernent of the		18	Retrieve M	II.	m ODM sou	rce using (CRF) Item Name		Genera	te WhereClause automatically	
Retrieve Meta	Intern Deministration of Provide Office Content in		18	Retrieve M	II III	m ODM sou	rce using (CRF) Item Name	Remove row	Genera	te WhereClause automatically	

We may e.g. want to remove rows, as we never have the specific test code (in FATESTCD) used in

our study. We can also already assign a source and origin (like the CRF page number(s)), add comments, etc..

If we click on one of the "where clause" definitions (last column) and use the button "Show 'Where' clause", we e.g. get:

OID:	W	C.CVFARS.C118936.ACMITYPE	
Comment:			External document for comment
		Show 'Where' clause	
	Where-Clause Exp	Number of RangeChecks: 1	
	(i) where F	ATESTCD EQ 'ACMITYPE'	
c	omparator: EQ 💌 Item Oli	FA.FATESTCD ▲ FA.FATEST FA.FAOBJ FA.FAOBJ FA.FACAT FA.FASCAT FA.FASCAT D: FA.FAORRES FA.FAORRESU FA.FASTRESC FA.FASTRESU FA.FASTRESU FA.FASTRESU ₩	CheckValue: ACMITYPE

We can get the same information by just hovering the mouse over the "Where Clause" cell:

Method	CodeList	WhereClause	
	CL.CVFAR.	WC.CVFARS.C118936.ACMITYPE	
	CL.CVFAF		
	CL.CVFAR	where FATESTCD EQ 'ACMITYPE'	
	CL.CVFAR	WC CVFARS.C119232 HELBENW	
	CL.CVFAR	WC.CVFARS.C119234.HFTHERIN	
	CL.CVFAR	WC.CVFARS.C119236.ISCETYP	
	CL.CVFAR	WC.CVFARS.C123443.NINVIMGC	
	CL.CVFAR	WC.CVFARS.C119238.NWSYMP	
	CL.CVFAR	WC.CVFARS.C119239.PCIAAC	
	CL.CVFAR	WC.CVFARS.C123424.STCTIMNG	
	CL.CVFAR	WC.CVFARS.C119579.STROKTYP	

When we have adapted the ValueList for our purposes, we still need to assign this ValueList to the FASTRESC variable:

Message	· X
i	Please do not forget to assign the created ValueList to a SDTM variable!
	ΟΚ

To do so, select it, and use the menu "Edit - SDTM Variable" (or use CTRL-E), leading to:

Edit Properties for SDTM Variable FACE.FASTRESC

?	OID:	FACE.FASTRESC
-	New OID	Edit
	Name:	FASTRESC
	SASFieldName:	FASTRESC
	Data type:	text
	Current Length:	80
	New Length:	
	Current Significant Digits:	
	New Significant Digits:	-1
	Current Role:	Result Qualifier
	New Role	Result Qualifier
	Current Role CodeList:	
	New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)
	Current Origin/Source:	NONE DEFINED YET
	Edit Origin/Source:	Edit
	Comment:	
	External document for comment	
	Current CodeList	NO CODELIST ASSIGNED
	New CodeList:	Select CodeList
	Description:	Character Result/Finding in Std Format
	current def:DisplayFormat:	
	New def:DisplayFormat:	
6	current ValueList OID:	NO VALUELIST ASSIGNED
	New ValueList OID	VLFA.FASTRESC
		OK Cancel

We now check the checkbox "New ValueList OID" and select the just created one from the dropdown:

Current CodeList	NO CODELIST ASSIGNED
New CodeList:	
Description:	Character Result/Finding in Std Format
current def:DisplayFormat:	
New def:DisplayFormat:	
current ValueList OID:	NO VALUELIST ASSIGNED
✓ New ValueList OID	VL.FA.FASTRESC
	VL.FA.FASTRESC
	NO VALUELIST

After our "OK", we can have a look at the visualization of the define.xml, e.g. using the menu "View - View define.xml in browser", leading to:

FACE (Finding About Clinical Events) - FINDINGS ABOUT [SDTMIG 3.3]

Variable	Where Condition	Label / Description	Туре	Role	Length or Display Format	Controlled Terms or ISO Format
STUDYID		Study Identifier	text	Identifier	80	
DOMAIN		Domain Abbreviation	text	Identifier	8	
USUBJID		Unique Subject Identifier	text	Identifier	60	
FASEQ		Sequence Number	integer	Identifier	80	
FAGRPID		Group ID	text	Identifier	80	
FASPID		Sponsor-Defined Identifier	text	Identifier	80	
FATESTCD		Findings About Test Short Name	text	Торіс	8	Cardiovascular Findings About Test Code [20 Terms]
FATEST		Findings About Test Name	text	Synonym Qualifier	40	Cardiovascular Findings About Test Name [20 Terms]
FAOBJ		Object of the Observation	text	Record Qualifier	80	
FACAT		Category for Findings About	text	Grouping Qualifier	80	
FASCAT		Subcategory for Findings About	text	Grouping Qualifier	80	
FAORRES		Result or Finding in Original Units	text	Result Qualifier	80	
FAORRESU		Original Units	text	Variable Qualifier	80	<u>Unit</u> [886 Terms]
FASTRESC VLM		Character Result/Finding in Std Format	text	Result Qualifier	80	
	FATESTCD = "ACMITYPE"	Item Definition for CVFARS for the case that CVTESTCD = ACMITYPE	text		29	CodeList for CVFARS for the case that <u>CVTESTCD = ACMITYPE</u> [7 Terms]
	FATESTCD = "CATMTHID"	Item Definition for CVFARS for the case that CVTESTCD = CATMTHID	text		30	CodeList for CVFARS for the case that <u>CVTESTCD = CATMTHID</u> • "ANGIOGRAPHY" • "AUTOPSY"
	FATESTCD = "HETYPE"	Item Definition for CVFARS for the case that CVTESTCD = HETYPE	text		29	CodeList for CVFARS for the case that CVTESTCD = HETYPE • "HEART FAILURE HOSPITALIZATION" • "URGENT HEART FAILURE VISIT"