

SDTM-ETL 4.4 User Manual and Tutorial

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Last update: 2024-02-01

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:

Variable: LBTESTCD

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 (LBTESTCD - 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:

Holter monitoring (HESTRESC).

Core: Exp

CDISC-CT Relations information:

Following CodeLists can be used (or a ValueList can be generated):

- C71150 (EGSTRESC - ECG Result):
Based on regular 10-second ECGs
- C120522 (HESTRESC - Holter ECG Results):
Based on Holter monitoring
- 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. as per sponsor data collection
practices.

Add CDISC Library information

View Document for:

SDTM Spec. v.1.7 SDTM-IG 3.3

OK

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:

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

OK

Also presenting us 3 possibilities.

Assigning the codelist

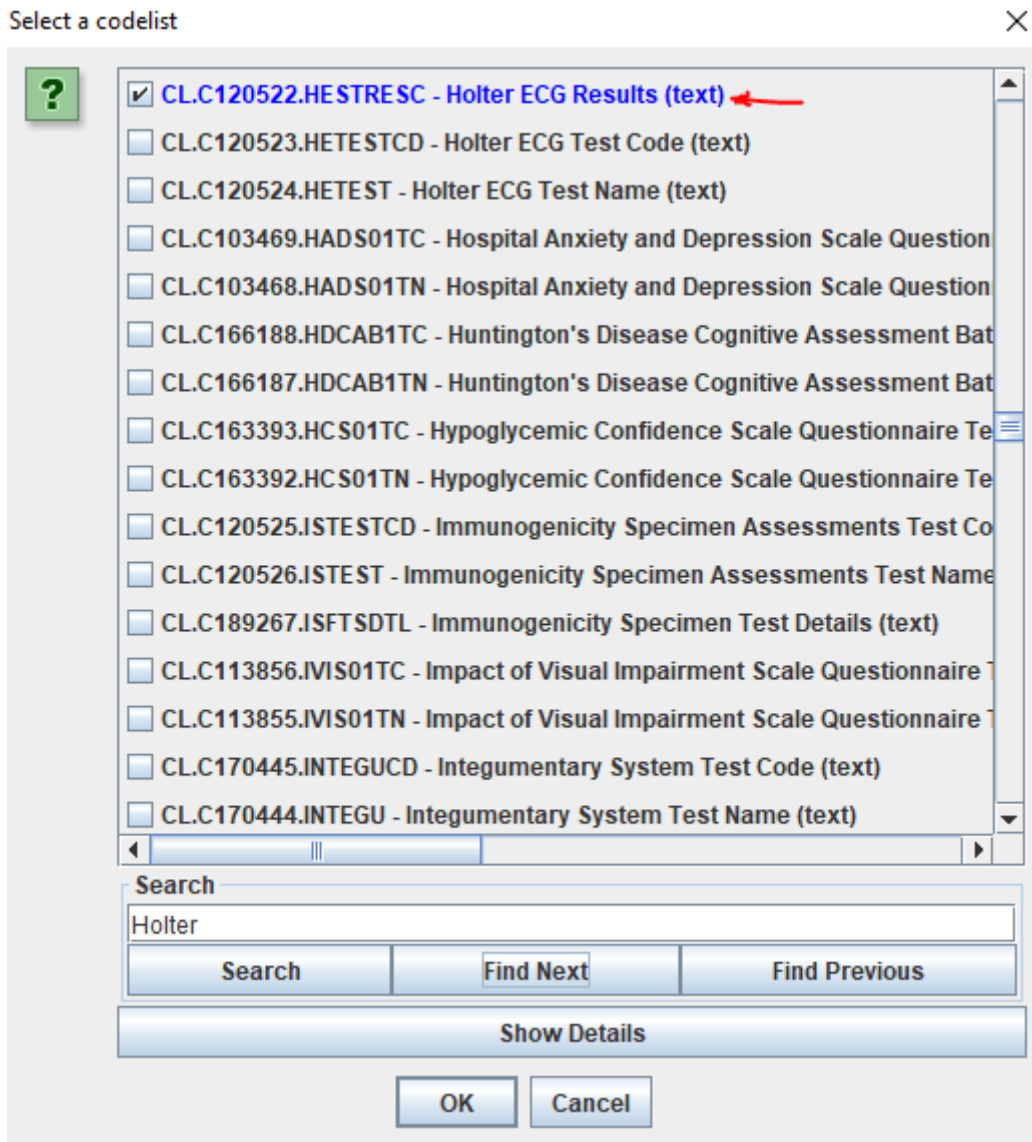
There are now several possibilities for assigning the codelist in the case of multiple codelists.

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:

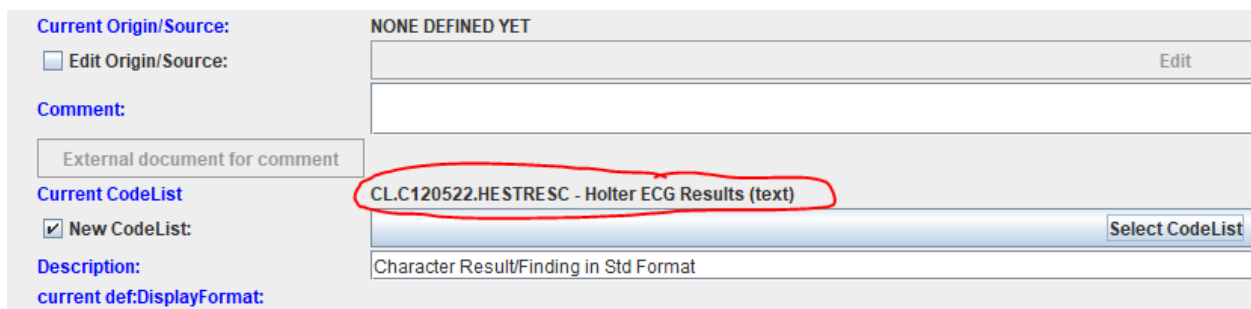
Edit Properties for SDTM Variable EG.EGSTRESC

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



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



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:

Select a codelist


✕

The dialog box contains a list of codelist options, each with a checkbox. The options are:

- CL.C100175.WPAI01TN - Work Productivity and Activity Impairment Quest
- CL.C130281.WD4TC - World Health Organization Disability Assessment Sc
- CL.C130280.WD4TN - World Health Organization Disability Assessment Sc
- CL.C130275.WD1TC - World Health Organization Disability Assessment Sc
- CL.C130274.WD1TN - World Health Organization Disability Assessment Sc
- CL.C130277.WD2TC - World Health Organization Disability Assessment Sc
- CL.C130276.WD2TN - World Health Organization Disability Assessment Sc
- CL.C130279.WD3TC - World Health Organization Disability Assessment Sc
- CL.C130278.WD3TN - World Health Organization Disability Assessment Sc
- CL.C130269.WD5TC - World Health Organization Disability Assessment Sc
- CL.C130268.WD5TN - World Health Organization Disability Assessment Sc
- CL.C130271.WD6TC - World Health Organization Disability Assessment Sc
- CL.C130270.WD6TN - World Health Organization Disability Assessment Sc
- CL.C130273.WD7TC - World Health Organization Disability Assessment Sc
- CL.C130272.WD7TN - World Health Organization Disability Assessment Sc
- NO CODELIST

Below the list is a search bar with the text "Search" and three buttons: "Search", "Find Next", and "Find Previous". Below these buttons is a "Show Details" button. At the bottom of the dialog are "OK" and "Cancel" buttons.

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:

 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 (HESTRESC - Holter ECG Results)
Based on Holter monitoring
Usage: SDTMIG v3.3

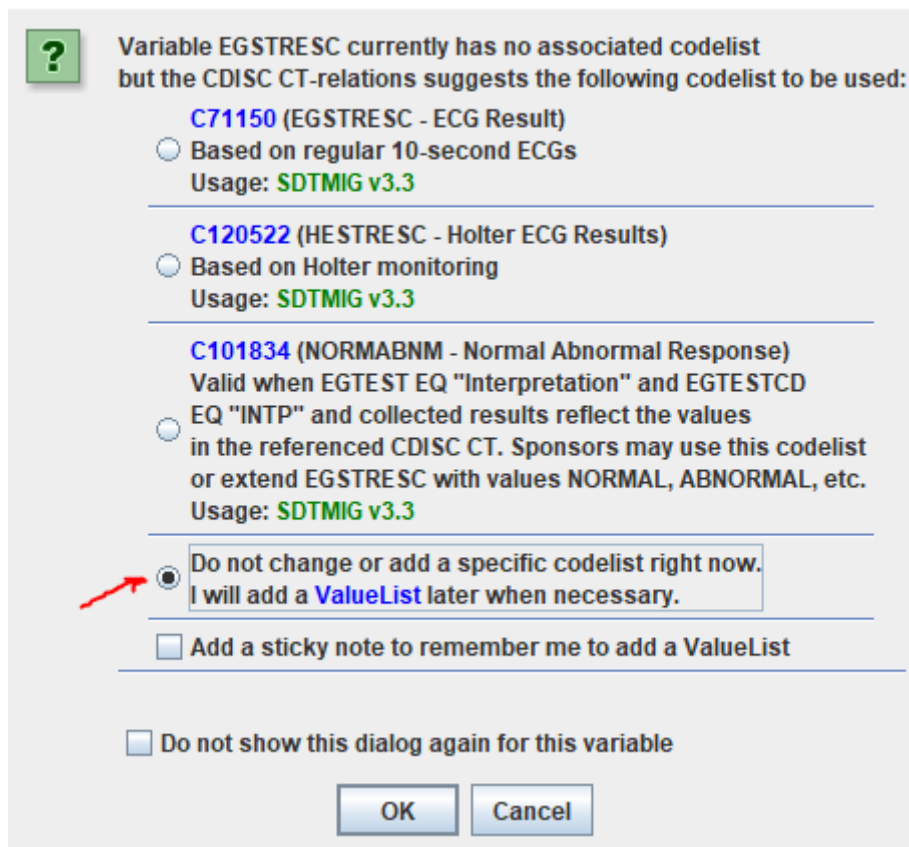
C101834 (NORMABNM - Normal Abnormal Response)
Valid when EGTEST EQ "Interpretation" and EGTESTCD EQ "INTP" and collected results reflect the values in the referenced CDISC CT. Sponsors may use this codelist or extend EGSTRESC with values NORMAL, ABNORMAL, etc.
Usage: SDTMIG v3.3

Do not change or add a specific codelist right now.
I will add a **ValueList** later when necessary.

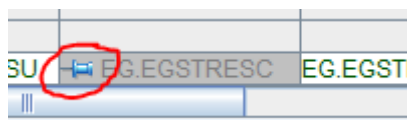
Add a sticky note to remember me to add a ValueList

Do not show this dialog again for this variable

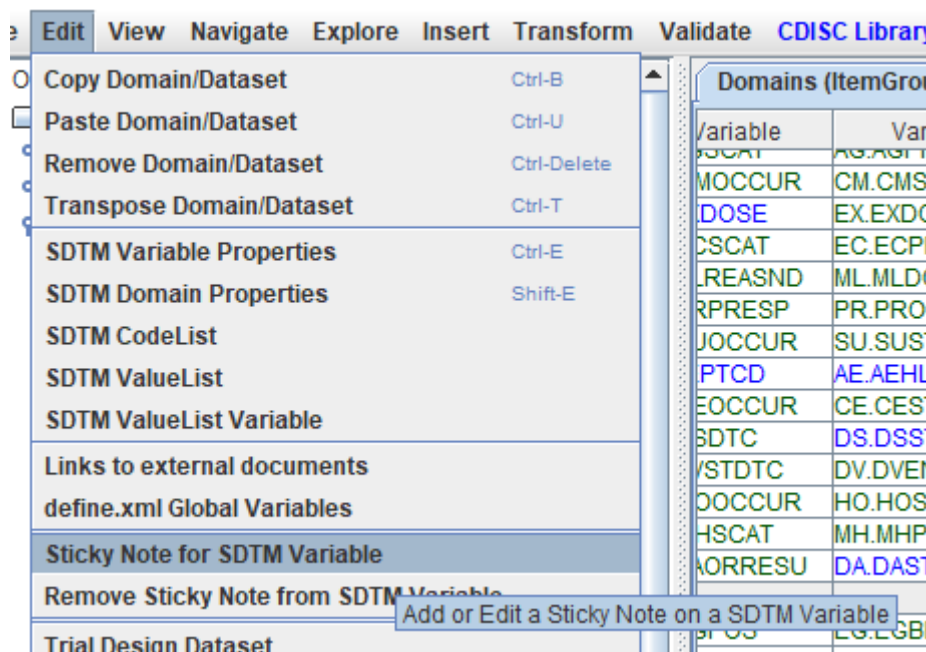
When we indeed want to assign a ValueList later, we select "Do not change or add a specific codelist now ...":



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:

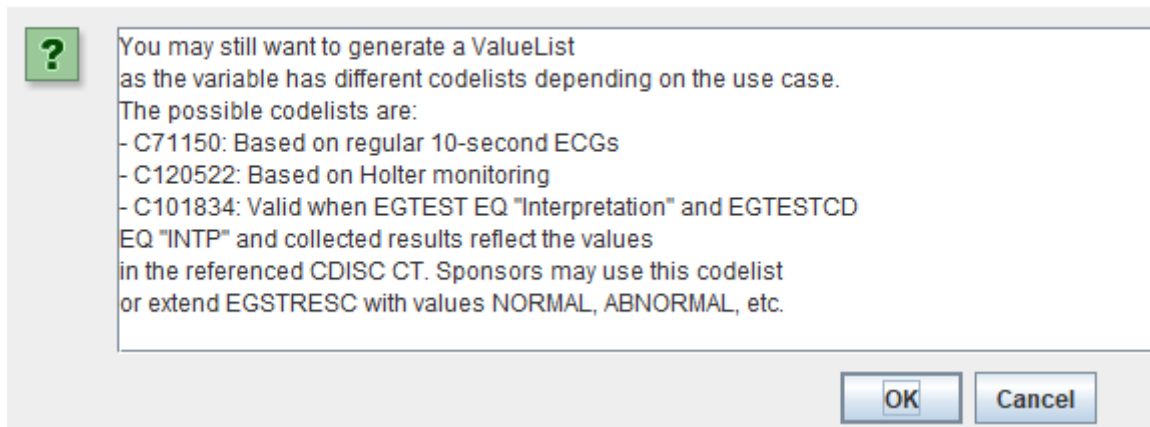


And when we then use the menu "Edit - Sticky Note for SDTM variable":



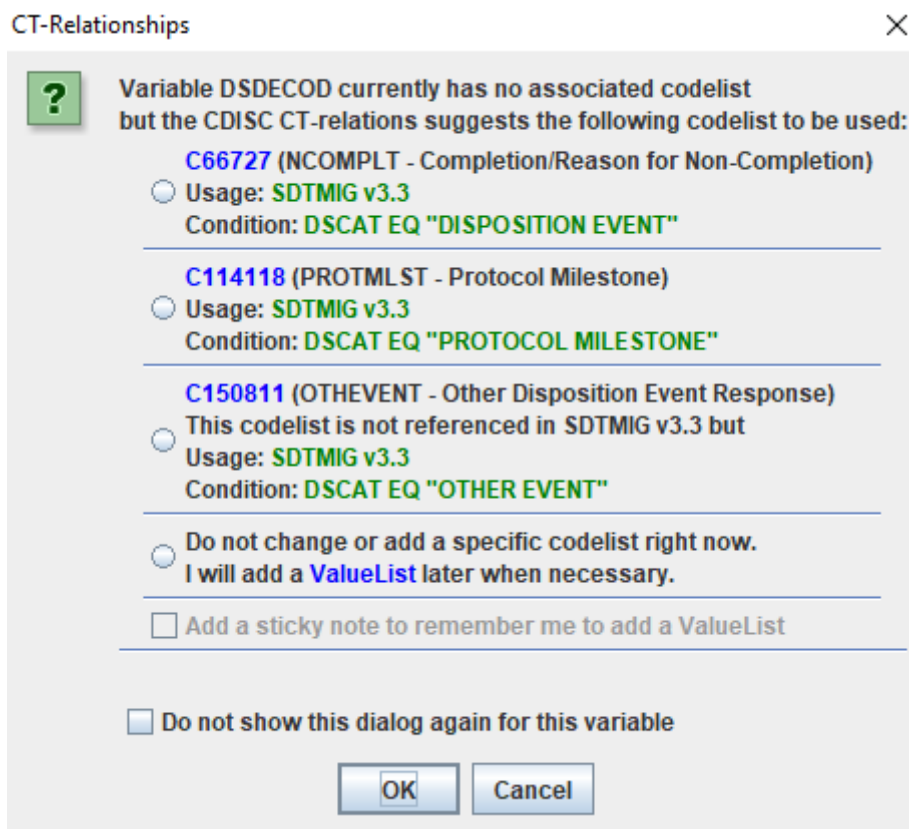
The "sticky note" is visualized and can be edited:

Sticky note editor for: EG.EGSTRESC



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.

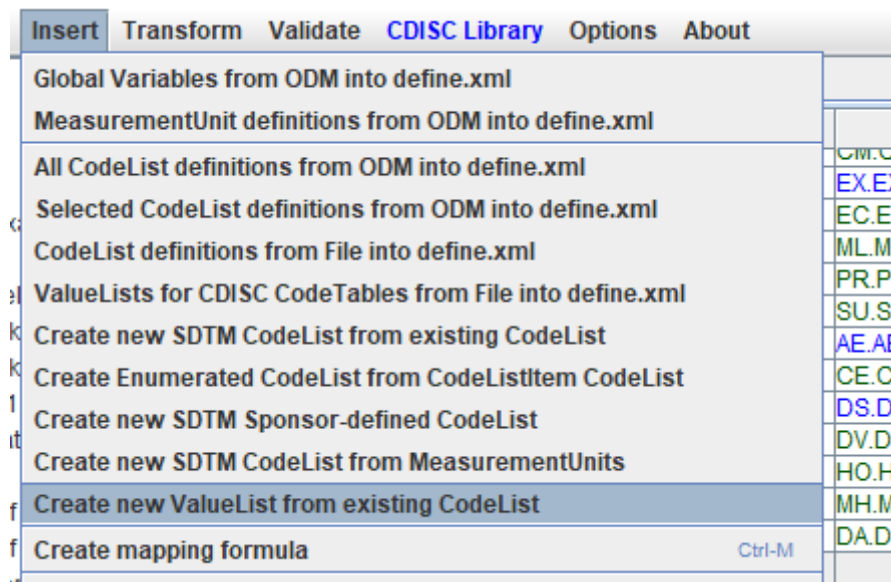
Similarly for DSDECOD, for which no initial codelist is present / assigned, when starting the mapping, the following dialog is displayed:



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":



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.DSCAT - 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.C150813.CDFATS - CDAD Findings About Test Name

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.C181174.CPTEST - Cell Phenotyping Test Name

CL.C181172.CELSTATE - Cell State Response

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

Search: DSCAT

Search Find Next Find Previous

Show Details

Create simple 'WhereClause' automatically

OK Cancel

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

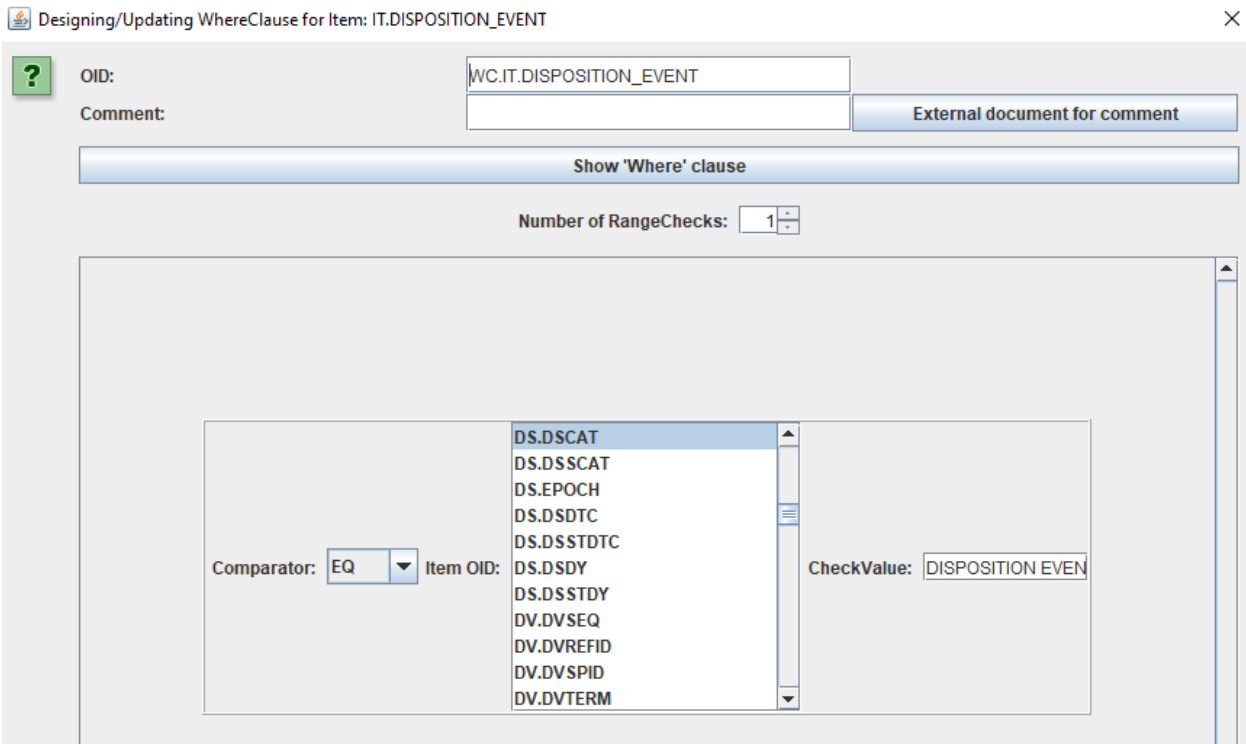
Create new SDTM ValueList from existing CodeList

CL.C74558.DSCAT - Category of Disposition Event

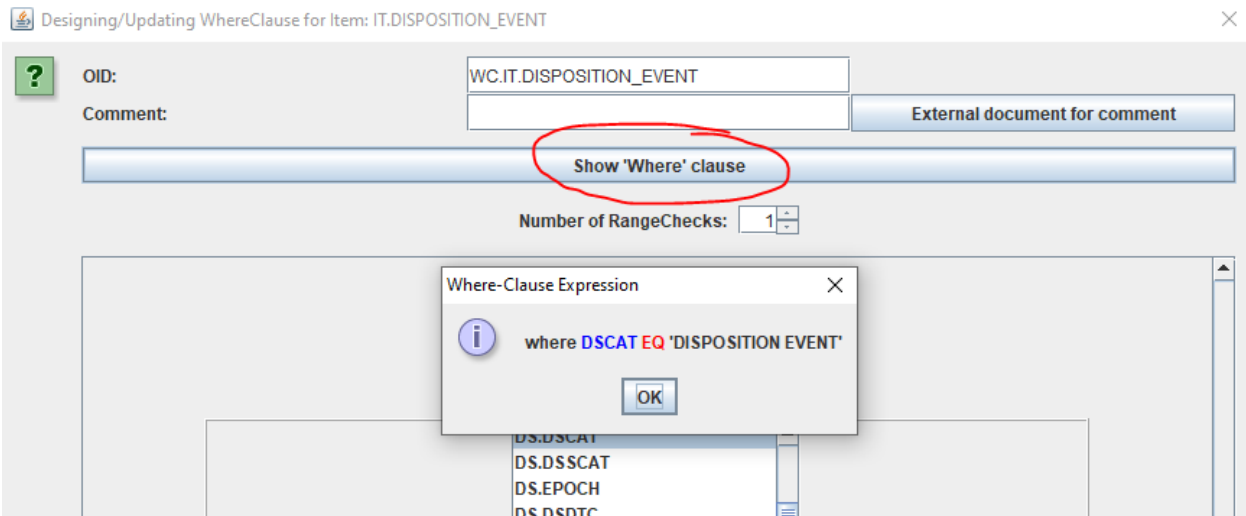
New OID: VL.CL.C74558.DSCAT

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

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



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):



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

CL.C74558.DSCAT - Category of Disposition Event				
New OID:				
OID	Name	Data Type	Length	Sign
IT.DISPOSITION_EVENT	DISPOSITION EVENT			
IT.OTHER_EVENT	OTHER EVENT	text		
IT.PROTOCOL_MILESTONE	PROTOCOL MILESTONE	integer		

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: VL.CL.C74558.DSCAT												
OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def.Display...	Method	CodeList	Where Claus	
IT.DISPOSITION_EVENT	DISPOSITION EVENT						DISPOSITION EVENT				WC.IT.DISPOSITION_EV	
IT.OTHER_EVENT	OTHER EVENT						OTHER EVENT				WC.IT.OTHER_EVENT	
IT.PROTOCOL_MILESTONE	PROTOCOL MILESTONE						PROTOCOL MILESTONE				WC.IT.PROTOCOL_MILE	

Leading to a "codelist selector":

Select a CodeList ✕

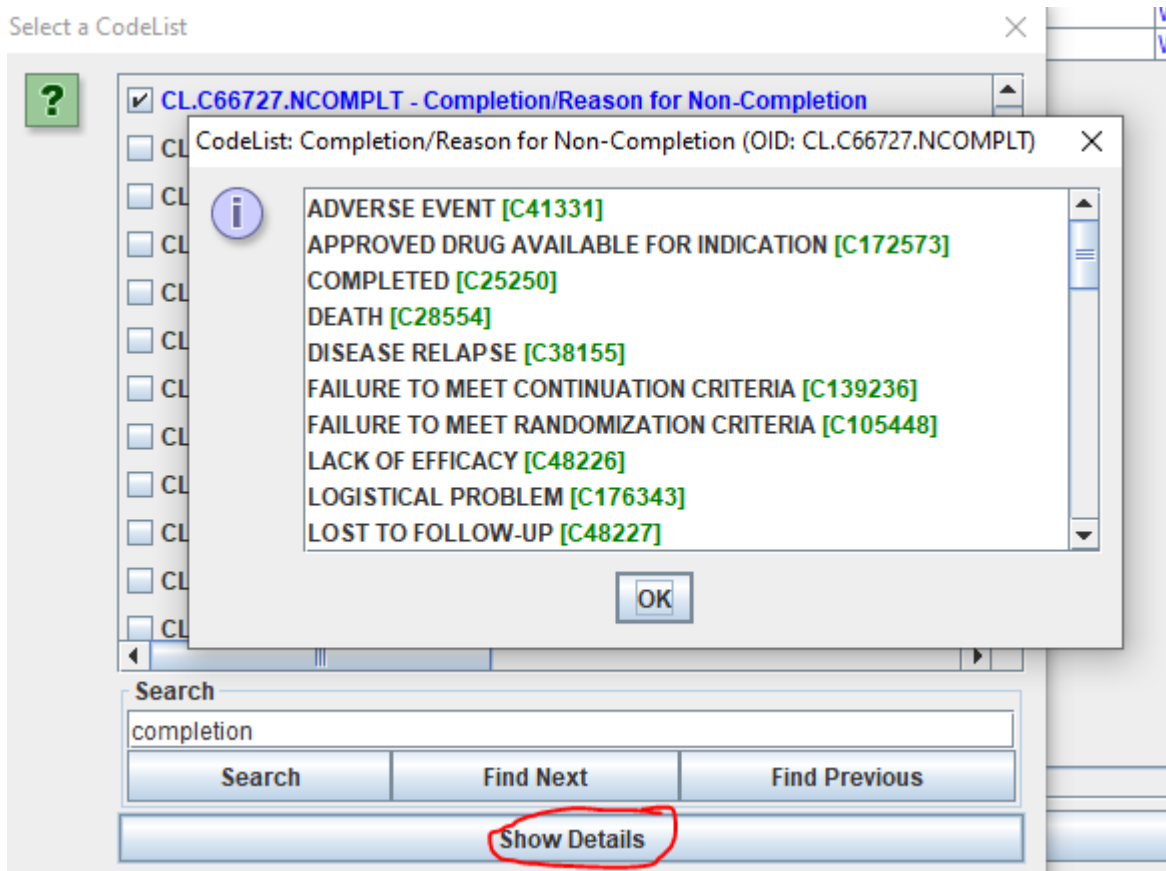
?

- CL.C66727.NCOMPLT - Completion/Reason for Non-Completion
- CL.C90018.CSTATE - Consciousness State
- CL.C101838.CCRCLSCD - Consensus Cardiac Classification System Test C
- 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

Show Details

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



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 new SDTM ValueList from existing CodeList

CL.C74558.DSCAT - Category of Disposition Event

New OID: VL.C74558.DSCAT

OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	defDisplay...	Method	CodeList	WhereClause
IT.DISPOSITION_EVENT	DISPOSITION EVENT	text	20				DISPOSITION EVENT			CL.C66727.NCOMPLT	WC.IT.DISPOSITION_EVENT
IT.OTHER_EVENT	OTHER EVENT	text	20				OTHER EVENT			CL.C150811.OTHEVENT	WC.IT.OTHER_EVENT
IT.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 [CDISC Dataset-JSON](#) which will probably be 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 Properties for SDTM Variable DS.DSDECOD

OID: <input type="checkbox"/> New OID	DS.DSDECOD
Name: SASFieldName:	DSDECOD
Data type:	text
Current Length: <input type="checkbox"/> New Length:	80
Current Significant Digits: <input type="checkbox"/> New Significant Digits:	-1
Current Role: <input type="checkbox"/> New Role	Synonym Qualifier
Current Role CodeList: <input type="checkbox"/> New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)
Current Origin/Source: <input type="checkbox"/> Edit Origin/Source:	NONE DEFINED YET
Comment: External document for comment	
Current CodeList: <input type="checkbox"/> New CodeList:	NO CODELIST ASSIGNED
Description: current def:DisplayFormat:	Standardized Disposition Term
<input type="checkbox"/> New def:DisplayFormat:	
current ValueList OID: <input type="checkbox"/> New ValueList OID	NO VALUELIST ASSIGNED
	VL.CL.C74558.DSCAT

OK Cancel

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

Current CodeList: <input type="checkbox"/> New CodeList:	NO CODELIST ASSIGNED
Description: current def:DisplayFormat:	Standardized Disposition Term
<input type="checkbox"/> New def:DisplayFormat:	
current ValueList OID: <input checked="" type="checkbox"/> New ValueList OID	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:

DSSPID		Sponsor-Defined Identifier	text	Identifier	80	
DSTERM		Reported Term for the Disposition Event	text	Topic	80	
DSDECOD VLM		Standardized Disposition Term	text	Synonym Qualifier	80	
	DSCAT = "DISPOSITION EVENT"	DISPOSITION EVENT	text		20	Completion/Reason for Non-Completion [42 Terms]
	DSCAT = "OTHER EVENT"	OTHER EVENT	text		20	Other Disposition Event Response <ul style="list-style-type: none"> • "FINAL CONTACT" • "SITE TRANSFER" • "TREATMENT UNBLINDED" • "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY"
	DSCAT = "PROTOCOL MILESTONE"	PROTOCOL MILESTONE	text		20	Protocol Milestone [11 Terms]
DSCAT		Category for Disposition Event	text	Grouping Qualifier	80	Category of Disposition Event <ul style="list-style-type: none"> • "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.

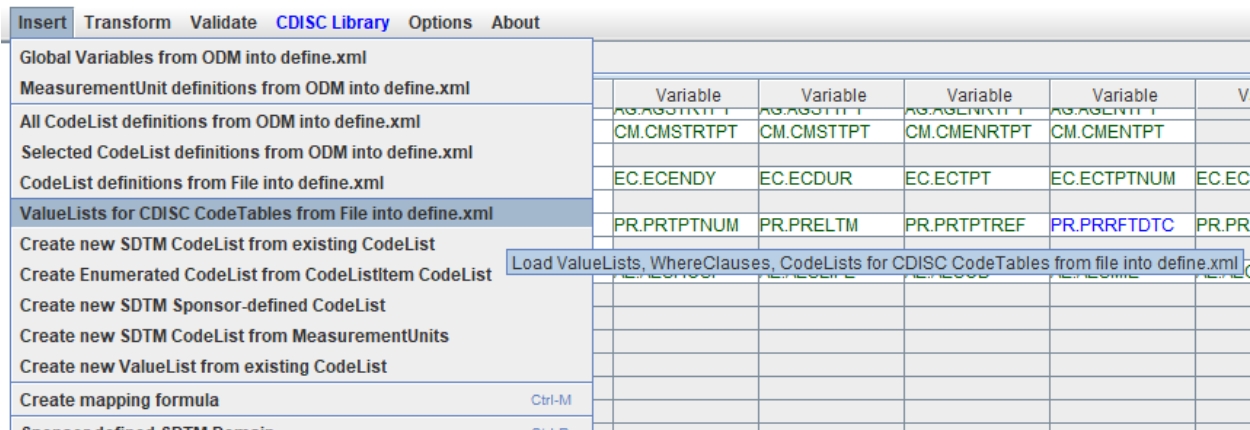
Some of our customers have reported 80% and more "reuse" of the mappings in the case of similar

studies in this way.

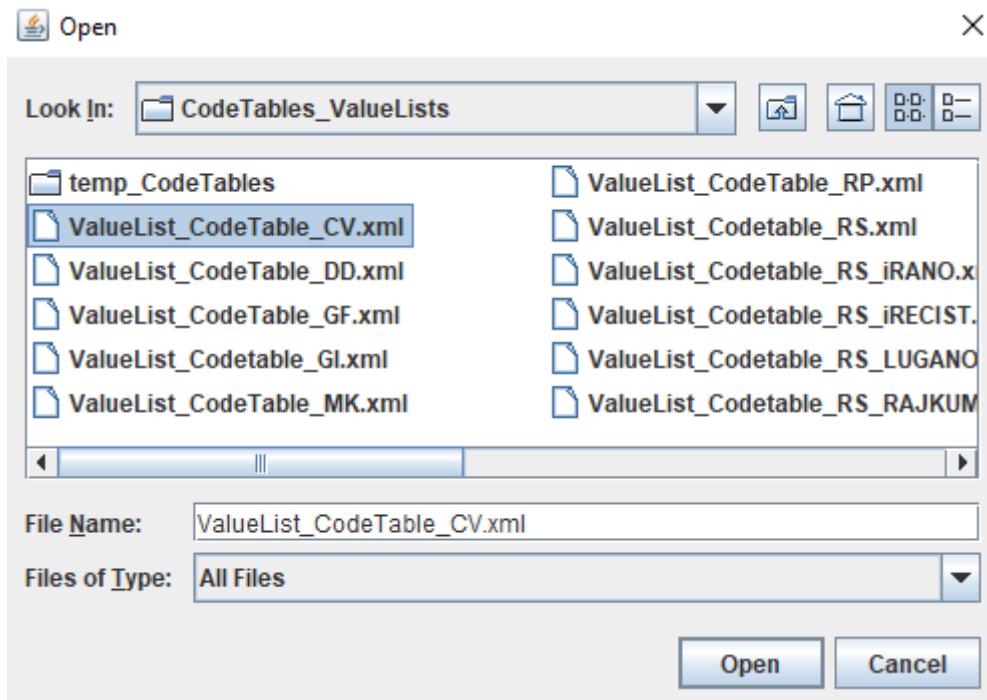
Pre-defined ValueLists

CDISC has published a number of "[code tables](#)", 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.

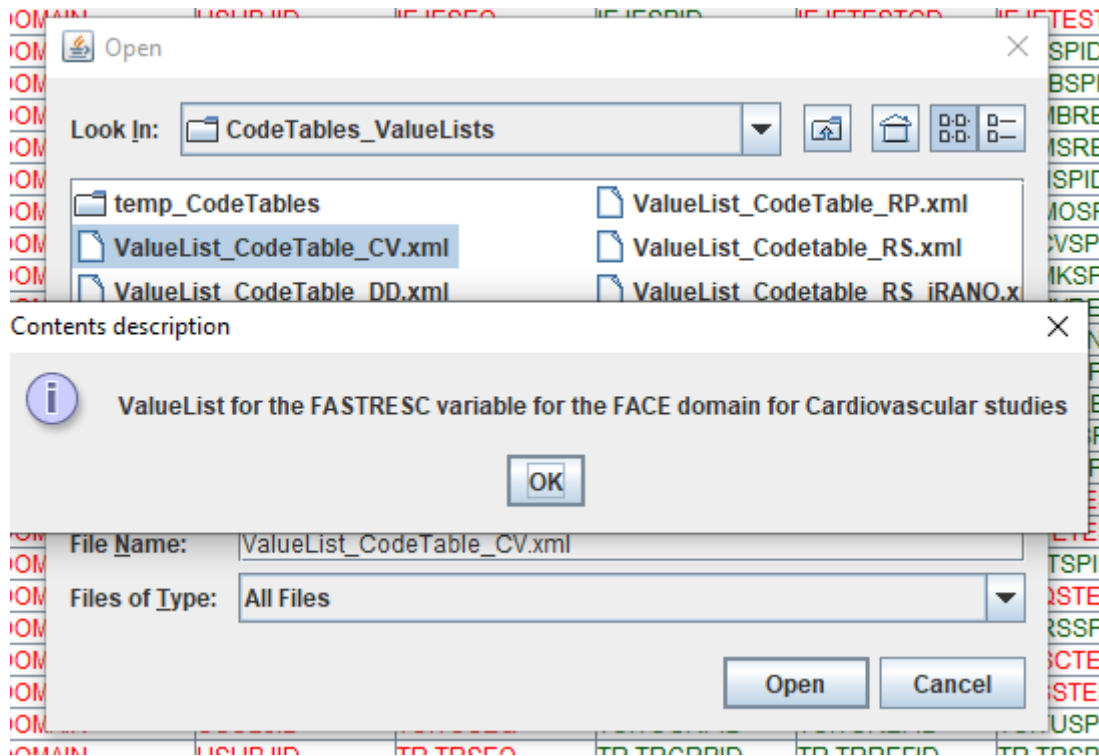
To load such a pre-defined ValueList, use the menu "Insert - ValueLists for CDISC Code Tables from File into define.xml":



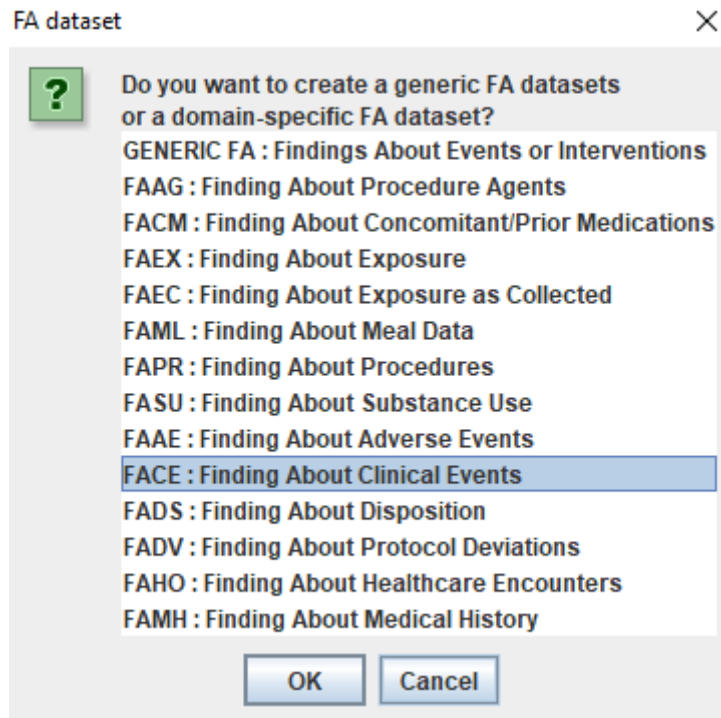
A list of available files will then be displayed:



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



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:



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:

FATESTCD associated codelist

? You may select to add a CDISC codelist to FATESTCD, depending on the type of findings area. You can however also create and add your own codelist.

Asthma Findings About Test Code

Cardiovascular Findings About Test Code

CDAD Findings About Test Code

COPD Codelist Name: Cardiovascular Findings About Test Code

Crohn's Members:

Diabetes ACMITYPE

Duchenne's CATMTHID

Ebola ENDPTIND

Lung HETYPE

Malaria HFLBFNW

Multiple HFPEFNW

Nutrition HFTHERIN

Pancreatic ISCDIND

Pediatric ISCETYP

Psoriasis MI12EXC

Schizophrenia NINVIMGC

Tuberculosis NWSYMP

Type PCIAAC

Vaccination PRSUCIND

PRUSTAT

STCTIMNG

STROKTYP

SYMPINDC

SYMSTDTC

VOC48IND

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:

Variable	StudyID	Domain	Parent	Child	Parent	Child	Parent	Child
TI	STUDYID	DOMAIN	TI.TESTCD	TI.TEST	TI.ECAT	TI.ESCAT	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			
OI	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

Name: FATESTCD

SASFieldName: FATESTCD

Data type: text

Current Length: 8

New Length: 8

Current Significant Digits: -1

New Significant Digits: -1

Current Role: Topic

New Role

Current Role CodeList: CL.MEDDRA - MedDRA Adverse Events Dictionary (text)

New Role CodeList

Current Origin/Source: NONE DEFINED YET

Edit Origin/Source:

Comment:

External document for comment

Current CodeList: CL.C119015.CVFATSCD

New CodeList:

Description: Findings About Test Short Name

current def:DisplayFormat:

New def:DisplayFormat:

current ValueList OID: **NO VALUelist ASSIGNED**

New ValueList OID

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

Name: FASTRESC

SASFieldName: FASTRESC

Data type: text

Current Length: 80

New Length: 80

Current Significant Digits: -1

New Significant Digits: -1

Current Role: Result Qualifier

New Role

Current Role CodeList: CL.MEDDRA - MedDRA Adverse Events Dictionary (text)

New Role CodeList

Current Origin/Source: NONE DEFINED YET

Edit Origin/Source:

Comment:

External document for comment

Current CodeList: NO CODELIST ASSIGNED

New CodeList:

Description: Character Result/Finding in Std Format

current def:DisplayFormat:

New def:DisplayFormat:

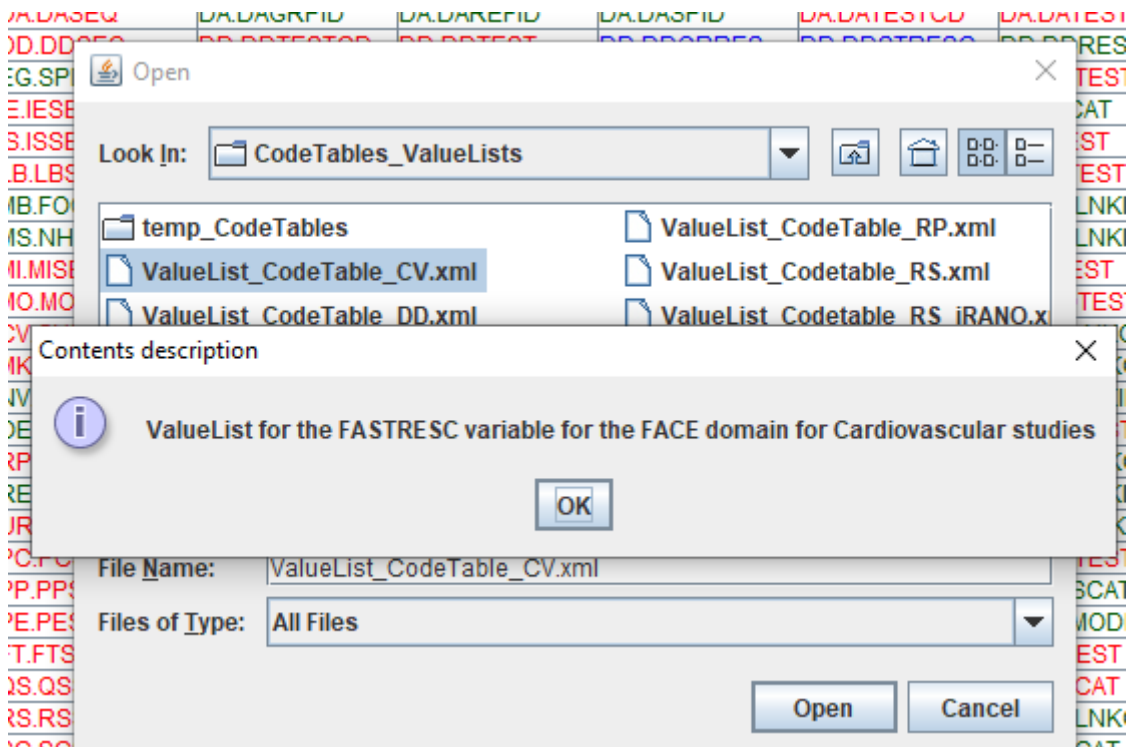
current ValueList OID: **NO VALUelist ASSIGNED**

New ValueList OID

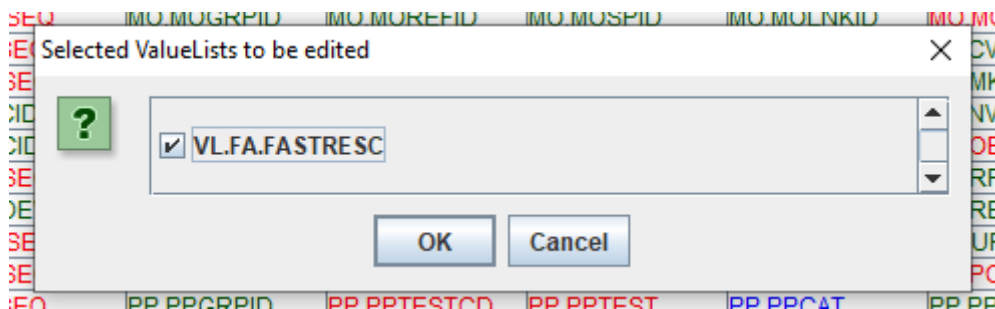
OK Cancel

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.

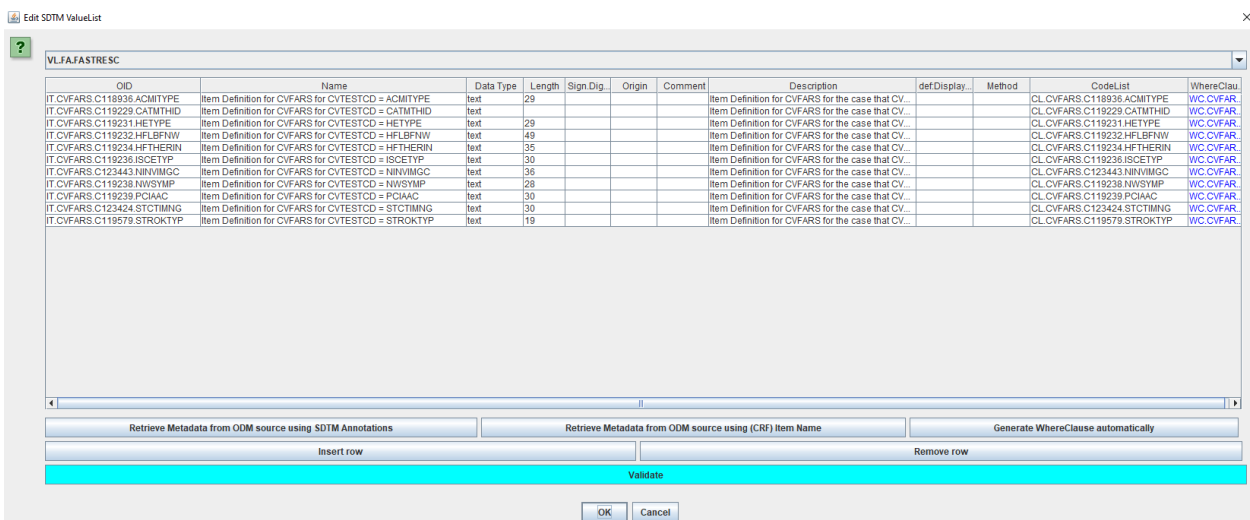
We can now import the ValueList (generated from the CDISC code tables) that we need by using the menu "Insert - ValueLists for CDISC Code Tables from File into define.xml", and select the "CV" one:



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



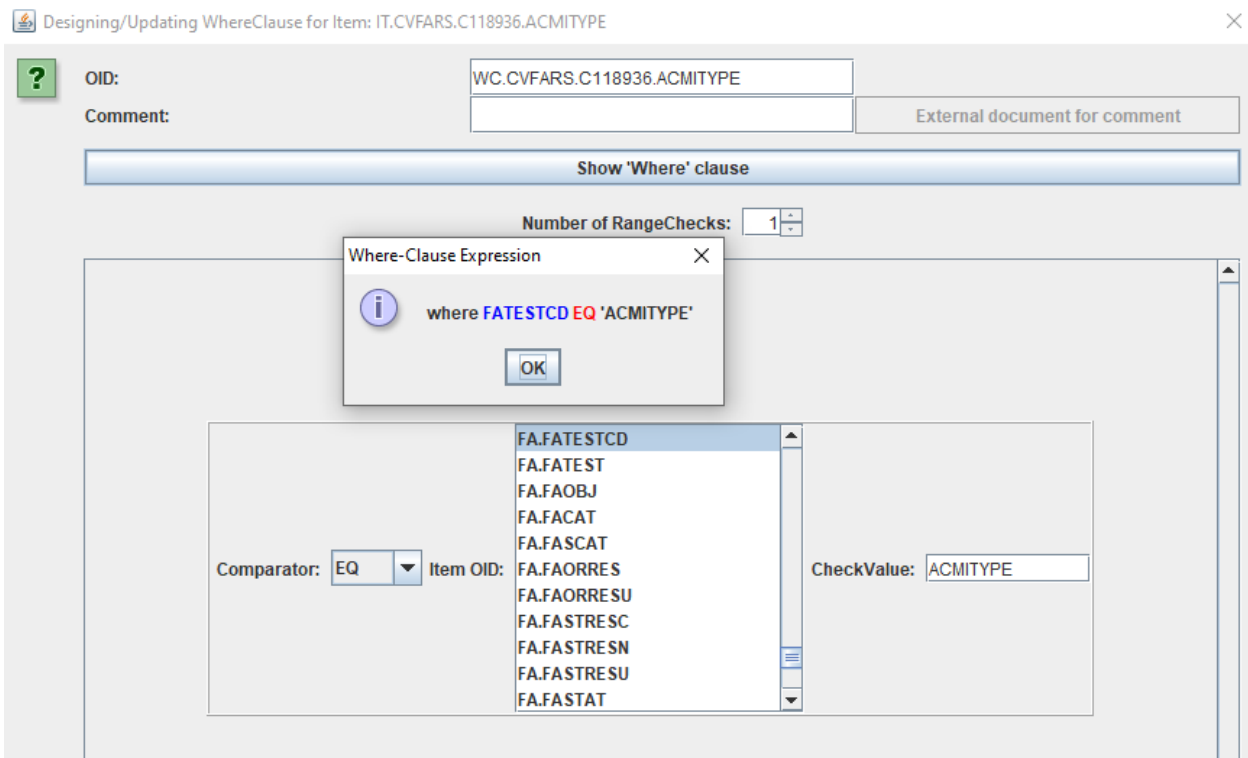
This is a good idea, as we may still want or need to make decisions:



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..

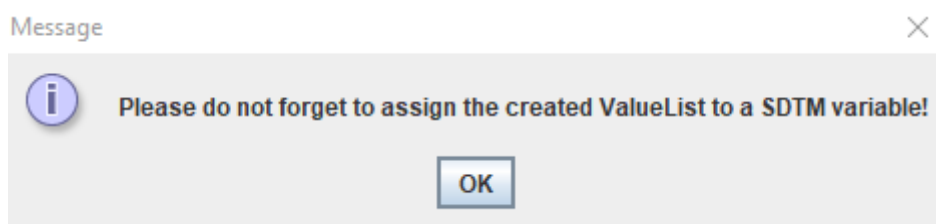
If we click on one of the "where clause" definitions (last column) and use the button "Show 'Where' clause", we e.g. get:



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.CVFAR...	WC.CVFARS.C119229.CATMTHID	
CL.CVFAR...	WC.CVFARS.C118936.ACMITYPE	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:



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: <input type="checkbox"/> New OID	FACE.FASTRESC
Name:	FASTRESC
SASFieldName:	FASTRESC
Data type:	text
Current Length:	80
<input type="checkbox"/> New Length:	80
Current Significant Digits:	
<input type="checkbox"/> New Significant Digits:	-1
Current Role:	Result Qualifier
<input type="checkbox"/> New Role	Result Qualifier
Current Role CodeList:	
<input type="checkbox"/> New Role CodeList	CL.MEDDRA - MedDRA Adverse Events Dictionary (text)
Current Origin/Source:	NONE DEFINED YET
<input type="checkbox"/> Edit Origin/Source:	Edit
Comment:	
External document for comment	
Current CodeList	NO CODELIST ASSIGNED
<input type="checkbox"/> New CodeList:	Select CodeList
Description:	Character Result/Finding in Std Format
current def:DisplayFormat:	
<input type="checkbox"/> New def:DisplayFormat:	
current ValueList OID:	NO VALUELIST ASSIGNED
<input type="checkbox"/> New ValueList OID	VL.FA.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
<input type="checkbox"/> New CodeList:	
Description:	Character Result/Finding in Std Format
current def:DisplayFormat:	
<input type="checkbox"/> New def:DisplayFormat:	
current ValueList OID:	NO VALUELIST ASSIGNED
<input checked="" type="checkbox"/> 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	Type	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	Topic	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	Unit [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 CVTESTCD = ACMITYPE [7 Terms]
	FATESTCD = "CATMTHID"	Item Definition for CVFARS for the case that CVTESTCD = CATMTHID	text		30	CodeList for CVFARS for the case that CVTESTCD = CATMTHID • "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"