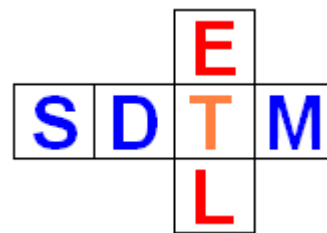


SDTM-ETL 3.1 User Manual and Tutorial

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Creating and working with Subject Global Variables

Some variables are used in different domains for calculations. Typical examples are the “Reference Start Date” (DM.RFSTDTC) and the “Reference End Date” (DM.RFENDTC).

They are e.g. used for the calculation of durations (e.g. AE), visit days (VISITDY) and the “End Relative to Reference Period” (--ENRF) variables.

Until v.1.5 of the software, the mapping for variables such as RFSTDTC and RFENDTC need to be generated over again, or copied-and-pasted from the DM domain.

As of version 1.6 of the software, it is possible to define “subject global variables” and provide mappings for them, and then use these variables in any other domain. The naming “subject global” has been chosen to reflect that such a variable is global within the scope of a subject, as e.g. the reference start date can be different for each subject.

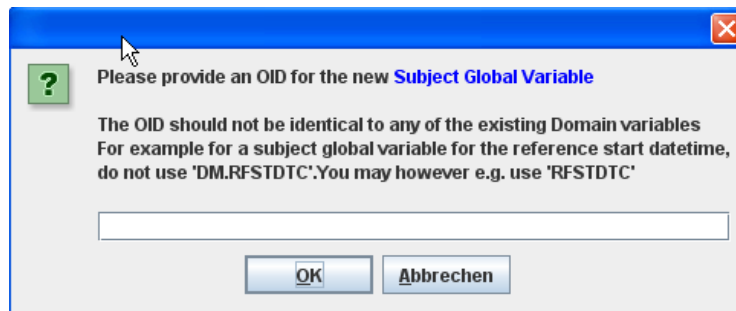
In order to create “subject global variables”, use the menu “Insert -> Global Subject Variables Domain”.

The screenshot shows the 'Insert' menu on the left and a table of domains on the right. The 'Global Subject Variables Domain' option is highlighted in the menu. The table lists domains and their associated variables.

	STUDYID	DOMAIN
RELREC	STUDYID	RDOMAIN
SUPPQUAL	STUDYID	RDOMAIN
MyStudy:GLOBAL		
MyStudy:DM	STUDYID	DOMAIN
MyStudy:QS	STUDYID	DOMAIN
MyStudy:SV	STUDYID	DOMAIN
MyStudy:PE	STUDYID	DOMAIN

This creates an empty domain with the name “GLOBAL”. This special domain cannot be copied (only one instance is allowed), and should come as the first domain in the list of study-specific domains (the software takes care of that). It can also not be moved.

One can then define a set of subject global variables within this “special” domain, using the menu “Insert -> New SDTM Variable” or simply by a double-click in an empty cell,



and use drag-and-drop or the variable editor to generate the mappings. It is important that such “global” variables are not given an OID that is already used in any of the other domains. For example, it is not a good idea to use “DM.RFSTDTC”, “DM.RFENDTC”, or “TEMP” as OID for such a variable. Instead one can however e.g. use “RFSTDTC” and “ENDTC” or “GLOBAL.RFSTDTC” and “GLOBAL.RFENDTC”.

RELREC	STUDYID	RDOMAIN	USUBJID	IDV#
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDV#
MyStudy:GLOBAL	RFSTDTC	RFENDTC		
MyStudy:DM	STUDYID	DOMAIN	USUBJID	SUE
MyStudy:QS	STUDYID	DOMAIN	RFENDTC	QS.1
MyStudy:SV	STUDYID	DOMAIN	Mandatory: No	SV.1
MyStudy:PE	STUDYID	DOMAIN	OrderNumber: 2	PE.1
MyStudy:AE	STUDYID	DOMAIN	Role: GLOBAL	AE.1
MyStudy:VS	STUDYID	DOMAIN	USUBJID	VS.1

The “subject global” variables can then be referenced in any other domain mapping. For example for the variable VSDY:

```

The Transformation Script
$VS.VSDY = datediff($VS.VSDTC,$RFSTDTC) + 1;

```

The “subject global” \$RFSTDTC variable is used in the calculation for the date difference between the VS “date/time of collection” (VS.VSDTC - which was already defined in the same domain) and the “reference start date/time”. One day has to be added as SDTM defines the first day of the study as day “1” (instead of day “0”).

Remark that local testing on real clinical data in mappings where “subject global” variables are used is not possible, as the variable is not “in scope”.

The “Subject Global” domain is removed when doing a “cleaned” export of the define.xml, and is omitted when validating the underlying define.xml structure using OpenCDISC or using the SDTM-ETL's own validator.

The distribution contains a sample file “MyStudy_AE_Domain_with_GLOBAL_define.xml” demonstrating this new feature.