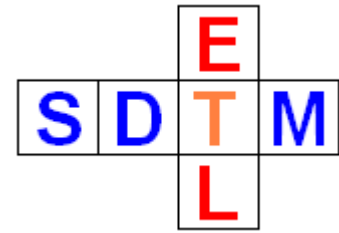# SDTM-ETL 4.4 User Manual and Tutorial

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Tutorial: Using user-defined default mapping descriptions

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Introduction

One of the requirements of the Define-XML standard is that, when the "Origin" is "Derived", a "MethodDef" element must be present and referenced, containing at least a description of the derivation method. This description then appears in the visualization when using the stylesheet. For example:

RFPENDTC		Date/Time of End of Participation	date	Record Qualifier		ISO 8601		Derived (Source: Sponsor) The latest date of assessment for the subject as determined by the End of Study Form, any scheduled assessments, Adverse Events, or Concomitant Medications.
DTHDTC		Date/Time of Death	date	Record Qualifier		ISO 8601		Collected (Source: Investigator) Annotated CRF [26 ⧉]
DTHFL		Subject Death Flag	text	Record Qualifier	1	No Yes Response, subset for variables with only "Y" or null values • "Y" = "Yes"		Derived (Source: Sponsor) If DTHDTC is populated then DTHFL='Y'

helping the reviewer understanding how the derivation was performed.

In SDTM-ETL, when a variable is mapped, the mapping script is kept in the same "MethodDef", and if nothing special is done, the mapping description is simply "SDTM-ETL mapping for ...", e.g.
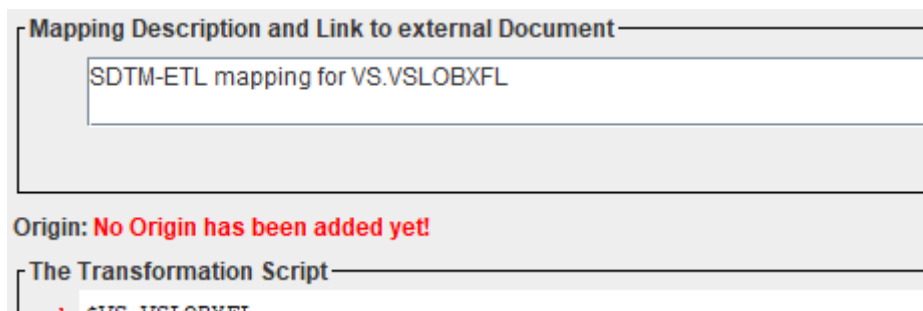

which one usually want to replace by a text that better describes the method used.

When one then uses the menu "File - Save cleaned define.xml", the mapping script will be removed, but the mapping description will be kept, at least (depending on the options selected) for the "derived" variables.

Adding the mapping descriptions for all the (at least) "derived" variables can be a tedious task, so we looked for a method to automate this, with the user still being in full control.

The option "Add default mapping descriptions from file"

As of version 4.4 of SDTM-ETL, it is possible to keep the user's "default" mapping instructions in a file "default_mapping_instructions.txt", which resides in the main folder where the software is installed:
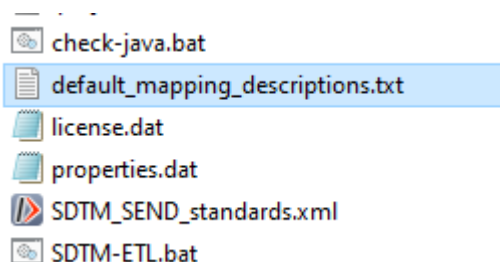
A prototype file "default_mapping_instructions.txt" is already present in the distribution, which can easily be adapted an extended by the user. It's contents are:

Each line (describing a user-defined "default" mapping descriptions) contains two parts:
- the variable name, to which the "-- notation" can be used, where the "--" can be replaced by any domain name
- the user-defined "default" mapping descriptions
the two fields are separated by a colon.

So the line "--DY: Study day relative to RFSTDTC. Date - RFSTDTC + 1 if on or after RFSTDTC. Date - RFSTDTC if date precedes RFSTDTC" means:
By default, set the mapping description for any --DY variable (e.g. VSDY, LBDY, DSDY, but not DSSTDY) to "Study day relative to RFSTDTC. Date - RFSTDTC + 1 if on or after RFSTDTC. Date - RFSTDTC if date precedes RFSTDTC", but only when the option is set to "true".

The option can be set in two ways:

The first way is to set the option using the menu "Options - Settings":
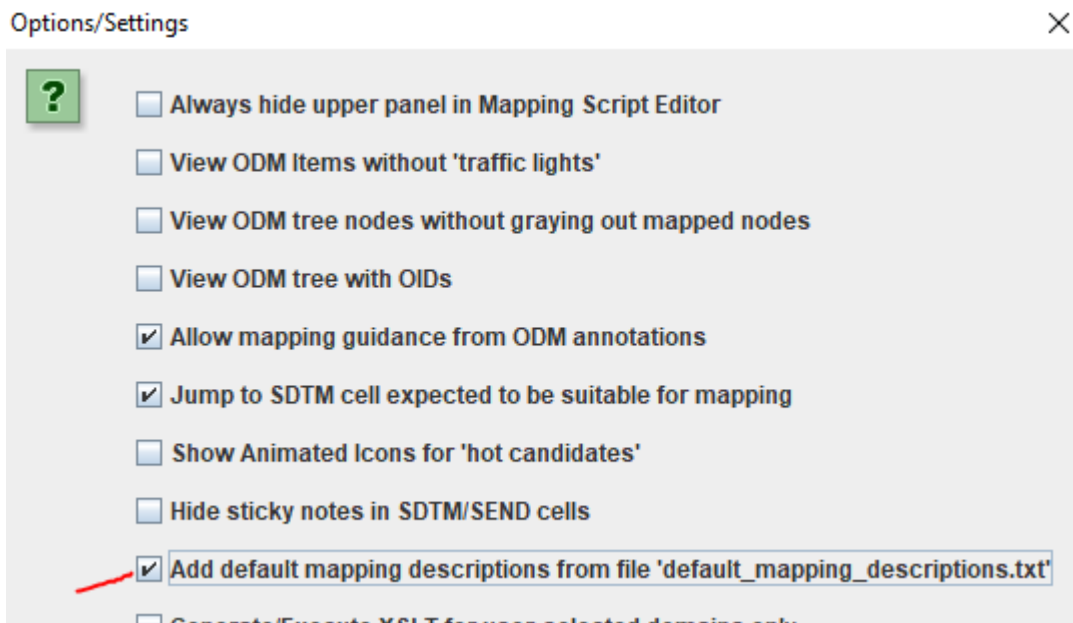
which can be switched on or off.

The second way is to add a line to the file "properties.dat" that can also be found in the folder where the software is installed. Essentially, this is a "start up" parameter that can be assigned the value "false" or "true" (default is "false"):

```
skipodmvalidation=true
# As of SDTM-ETL v.4.4: set user-defined "default" mapping descriptions
adddefaultmappingdescriptions=true
# postpone ODM tree recalculation after loading a define.xml
postponeodmtreenoderecalculation=true
# set number of minutes between define.xml autosave
numminutesforautosave=15
```

When the software is then started, it takes the setting as defined in the "properties.dat" file. The option can then still be changed using the menu "File - Edit Properties". Also during the mapping, the option can always be switched on or off.

Automated adding of the user-defined mapping descriptions

When the option is switched on, and editing the mapping of the variable is started (either by drag-and-drop, by double-click), the software will look whether the variable already has a mapping description.
If not, it reads the file "default_mapping_descriptions.txt" and tries to find a match between the variable for which the user-defined mapping description is desired, and the contents of the file. If a description is found, this e.g. leads to:

When nothing is found, the mapping description set will be "SDTM-ETL mapping for xxx" with "xxx" being the identifier for the variable.

The user can then still change the mapping description, which is kept, even when the mapping is edited again at a later stage. If however, the mapping description is completely removed, the software will try again to add the "user-defined" one the next time the mapping is edited.

If the option is switched on, and the system finds the description "SDTM-ETL mapping for ...", it will also try to replace it with the one from the file.

In our file "default_mapping_instructions.txt", we also find a user-defined mapping description for "--DY" variables. This means that is as well applies to e.g. "AEDY", "LBDY", "VSDY" (but not to any --STDY variables - these then need a separate line in the file). This leads e.g. for VSDY to:

If as well a user-defined mapping description for e.g. --DY and VSDY is provided, the latter will be taken when generating or editing the mapping for VSDY.

Conclusions

This new option "Add default mapping descriptions from file" can save a lot of time for the user when generating the mappings, and wanting to use the "cleaned define.xml" as the basis for a submission define.xml, which requires mapping descriptions for all "derived" variables.

Of course, it requires that all these "default" mapping descriptions are developed and written in the file "default_mapping_descriptions.txt", but this is a one-time exercise.