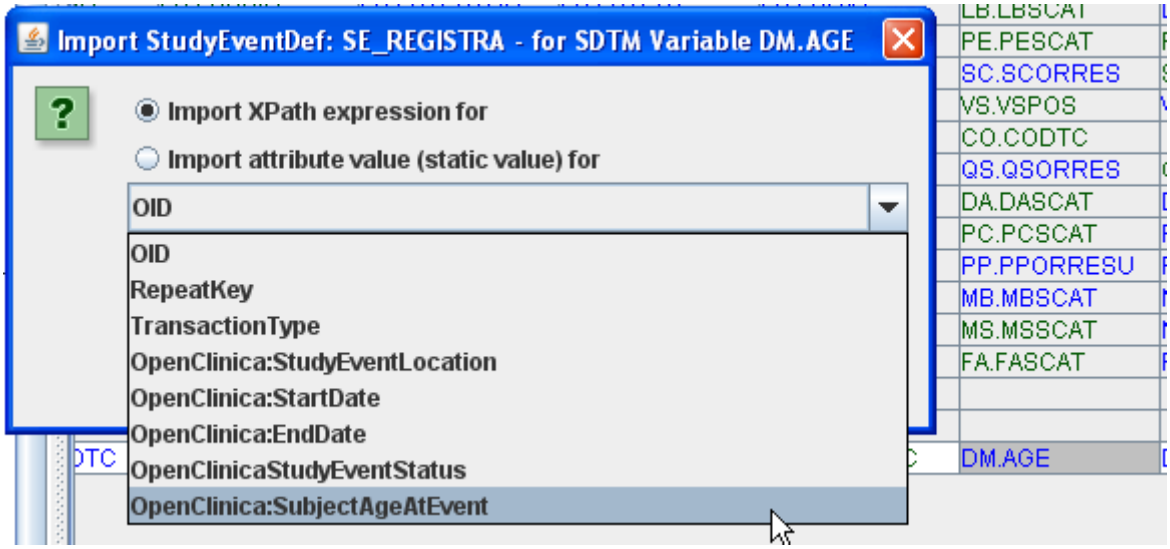
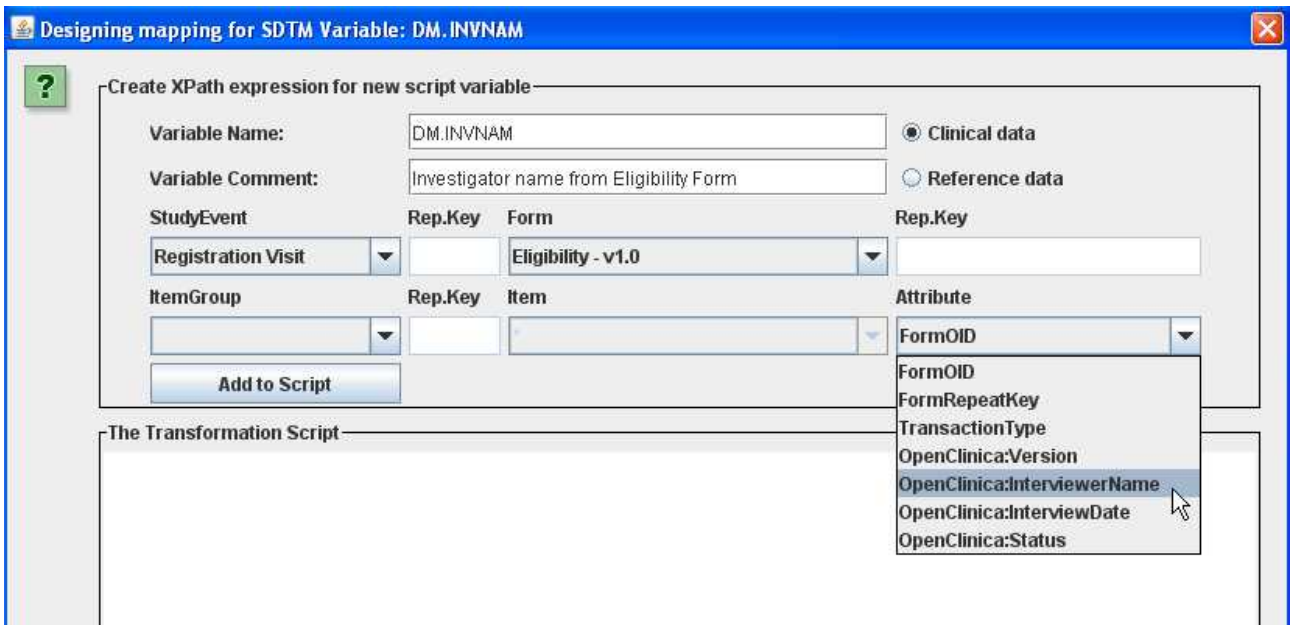
SDTM-ETL™
for OpenClinica users

Users of OpenClinica v.3 that also want to prepare SDTM datasets from their data, and that do not want to spend considerable amounts of money to (statistical) software to do so, now have a unique opportunity:
SDTM-ETLTM is an easy-to-use software package especially designed for setting up and executing mappings between ODM (such as exported by OpenClinica) and SDTM. Mappings can usually be defined by simple drag-and-drop, and when necessary, refined using the easy-to-learn scripting language. In most cases however, wizards will generate the scripts automatically.
SDTM datasets v.1.1 (SDTM-IG 3.1.1) or v.1.2 (SDTM-IG 3.1.2) can then be generated by executing the mappings on ODM files with clinical data.
The software has now been extended to support OpenClinica extensions to the ODM standard. This means that when doing drag-and-drop, the OpenClinica extension attributes will be presented to the user to be used in the mapping. For example, when doing a drag-and-drop from the "StudyEvent" level to the SDTM field DM.AGE, the user has the possibility to select the OpenClinica extension "SubjectAgeAtEvent" for usage in the mapping:

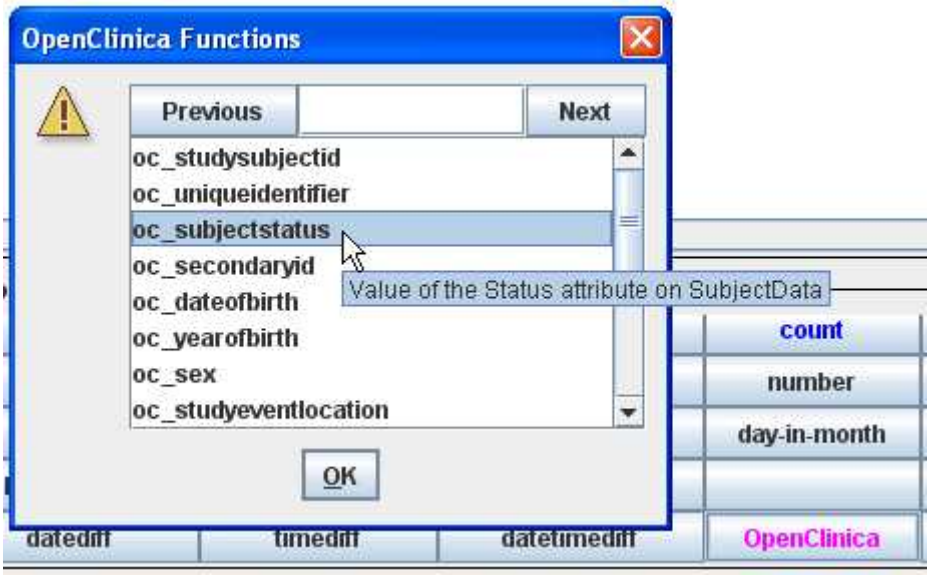


Also the OpenClinica extensions "StartDate" and "EndDate" can e.g. be used for mapping to the SDTM variables RFSTDTC ("Reference Start Date") and RFENDTC ("Reference End Date").
Similarly, when doing drag-and-drop from the Form level, the OpenClinica extensions "InterviewerName" and "InterviewDate" can be used e.g. for the SDTM variables "INVNAM" and for any of the "--DTC" SDTM variables. The latter can then be further used for calculating the "--DY" (visit day) for any of the other SDTM domains using the build-in SDTM-ETL functions.
The "ReasonForNull" extension attribute will in many cases be extremely useful for mapping to any of the SDTM "--REASND" variables.

Some users prefer to not use drag-and-drop, but to use the "XPath Designer" wizard, allowing to select items in order to create the expression for the SDTM variable automatically. Also here, the OpenClinica extensions have been implemented. For example, for the "Investigator's name" (DM.INVNAM):



Special functions for working with the OpenClinica extensions can be accessed from the mapping functions panel. A simple click on the "OpenClinica" button presents a list of special functions:



At the moment of writing, 17 special OpenClinica functions have been implemented. Additionally, users can write their own specialized functions for easy reuse in different studies.

SDTM-ETL™ also always keeps a define.xml synchronized with the mappings that are being developed, so that at the end, a few button clicks only suffices to produce a submission-ready define.xml.

By using OpenClinica v.3 in combination with SDTM-ETL™ for OpenClinica Users, CROs can now save huge amounts of money and still provide sponsors end-to-end services from study design to delivery of SDTM datasets, including a ready-to-submit define.xml.