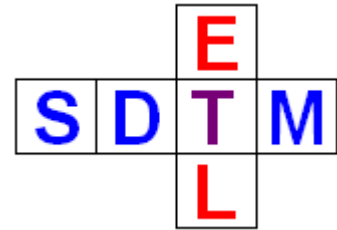# SDTM-ETL™

The user-friendly ODM – SDTM Mapping software package

Transforming CDISC ODM datasets with clinical data into SDTM datasets is not an easy process.

Therefore, XML4Pharma has developed a visual, easy-to-use mapping software package for defining and executing ODM to SDTM mappings, and to create and fill an SDTM database.

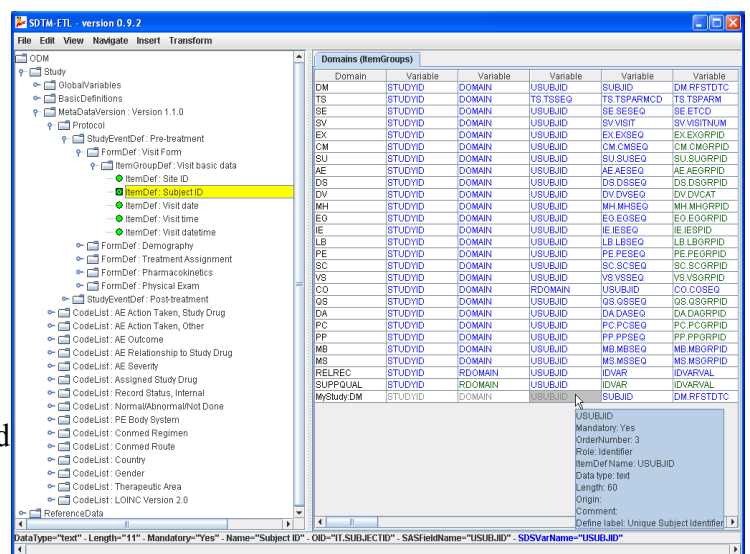The SDTM-ETL™ software package is a real ETL software tool allowing to:
Extract: ODM metadata and clinical data from ODM files
Transform: describe (even complicated) mappings between ODM and SDTM and execute them
Load: create an SDTM database and load the SDTM data into the database.

Mapping features:

- create mappings using drag-and-drop
- combine ODM data into a single SDTM variable
- perform calculations on ODM data to populate SDTM variables
- many mathematical and date/time functions provided
- "CDISC Notes" on each SDTM variable for background information
- easy-to-learn scripting language for complicated mappings
- many wizards provided for auto-generation of scripting snippets
- test mapping scripts on clinical data

Transformation features:

- mapping scripts are transformed into XSLT which is executed on the ODM clinical data, resulting in SDTM datasets in XML format (precursor of CDISC SDTM-XML) and/or SAS Transport (XPT) datasets. No knowledge of XSLT is however required.
- automated generation of SUPPQUAL domains when necessary
- offline transformation is possible
- generation of define.xml file (for submission to the FDA) from the study-specific domains and variables

Database features:

- create SQL statements for generating a relational SDTM database from the study-specific domains and variables
- Transform and load the generated SDTM records into the SDTM database.