

SDTM-ETL 3.0 New Features



SDTM-ETL 3.0 has a lot of new features. The most important ones are listed and explained in this document

Support for the newest CDISC standards

SDTM-ETL 3.0 has full support for the following new CDISC standards:

- [define.xml 2.0](#)
- [Dataset-XML 1.0](#)
- [newest CDISC Controlled Terminology](#) (december 2013)
- [SDTM 1.4 / SDTM-IG 3.2](#)

The user can now choose between define.xml 1.0 and define.xml 2.0 for keeping the mappings and exporting a „near-submission-ready“ define.xml. For new projects, the use of define.xml 2.0 is strongly encouraged.

Dataset-XML is a new XML-based format for submission of SDTM, SEND and AdAM data to the regulatory authorities, replacing the legacy SAS-XPORT format. The FDA is currently conducting a pilot in the use of this format, which has a lot of advantages over SAS-XPORT such as:

- no more 8-, 40- and 200-character limitations
- open, vendor-neutral format
- non-standard variables can be kept in the parent domain
- no more COVAL1, COVAL2, ... variables
- perfect fit with define.xml

This new format is also expected to boost the development of new tools, such as smart viewers, validation tools and analysis tools.

The user can choose between generating SDTM/SEND datasets in either CDISC Dataset-XML format or in classic SAS-XPORT format (or do both).

Full support is also delivered for SDTM 1.4 / SDTM-IG 3.2. When starting a new project, the user can choose between SEND 1.0, SDTM 1.2 (SDTM-IG 3.1.2) or 1.3 (SDTM-IG 3.1.3) or 1.4 (SDTM-IG 3.2). Also additional templates such as for Medical Devices and Associates Persons can be loaded additionally.

Graphical User Interface

As for each version of SDTM new domains are added, the user easily loses the overview. Therefore, it is now possible in SDTM-ETL 3.0 to hide domains in the GUI. This applies as well to template domains as to study-specific domains. Domains (table rows in the GUI) can be hidden or (re)displayed with a few mouse clicks only.

In SDTM-ETL 3.0, the user can even decide and select for which of the loaded domains the mappings are executed. Executing the mappings for a selection (or only one) of the loaded domains especially saves a lot of time during the testing of the mappings.

The open source „Smart Dataset-XML Viewer“ has been integrated into the software in a modular way, meaning that the user can easily replace the default copy of the viewer by his own one (e.g. an extended one). The viewer comes into action when the user selected to generate the SDTM/SEND

files in the new CDISC Dataset-XML format.

When inspecting clinical data from an ODM file, also the repeat keys can now be displayed (option).

The underlying define.xml file can now be displayed using the stylesheet (one can easily add his own one) either within the software (as before) or in the users favorite browser (IE, Firefox, Chrome, ...).

Vendor extensions support

SDTM-ETL does already have build-in support for OpenClinica and ClinCapture ODM exports. This support has now been extended with new features. Due to its modular structure, also support for other vendor extensions, such as for Medidata can easily be added.

When working with files with vendor extensions, SDTM-ETL 3.0 now allows to remove the vendor extension elements and attributes as a part of the loading procedure.

Other new features

An „autosave“ feature has been added: the system automatically saves a copy of the mappings (as a define.xml file) every 5 minutes. Using the „Options“ menu, the user can define the autosaving time interval.

When working with define.xml 2.0, „slices“ can be defined based on the „WhereClause“ elements. This means that the define.xml file that is produced during the mapping can be made „submission ready“. Also domain keys and sequence can easily be defined in a very user friendly way. The same applies for many other new elements and attributes of define.xml 2.0 (e.g. „pagelists“).

Features for generating valuelists from codelists have been further improved and made even more user friendly.

When generating SAS XPORT files, numeric values are now generated in double precision (was single precision before).

Generated Dataset-XML files can be validated against the currently loaded define.xml or against a define.xml file on disk.

Last but not least, the memory footprint has further been optimized, so that also extremely large ODM files with clinical data can now be processed with smaller memory requirements.

Features planned for version 3.1

- dataset editor for trial design datasets
- support for more vendor extensions (upon customer request)
- OpenCDISC validation for define.xml 2.0 and Dataset-XML files (we are currently waiting for OpenCDISC to release a new version of their software).