

## V2.6.0 Release Note – 27 Nov 2022

## ■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	New Release of Method Library	Feature Enhancement	A new version of Method Library (Library Version 20221114.01, Method Version V20221023.01), which include the following enhancements has been released: <ul style="list-style-type: none"> <li>- New Methods <b>copyUnique()</b> and <b>joinUnique()</b> that enable copying unique records only from source tables.</li> <li>- New Method <b>joinMultiple()</b> that enables copying multiple source values to single SDTM variable.</li> <li>- New Use Cases to derive <b>AETRTEM</b></li> <li>- New Use Cases to copy <b>CMDECOD</b> from normalized source tables</li> <li>- New Use Case to copy <b>CMCLAS/CMCLASCD</b> from normalized source tables</li> <li>- Updated Use Cased to derive <b>AESCAN/AESCONG/AESDISAB/AESDTH/AESHO SP/AESLIFE/AESOD/AESMIE</b> (N was derived for Y-only variables)</li> </ul>
2.	New MAPPING_REF_RANGE tab and enhanced REF_RANGE tab for SDTM spec	Feature Enhancement	A new MAPPING_REF_RANGE tab has been added to SDTM spec to enable copying reference ranges from source tables (rather than entering them into the REF_RANGE tab of SDTM spec). The REF_RANGE tab has also been updated to support optional Test Subcategory.
3.	New SUBJECT_LIST tab for SDTM spec	Feature Enhancement	A new SUBJECT_LIST tab has been added to SDTM spec to enable converting collected subject identifier to "formal" Subject ID (e.g. Screening ID to Subject ID) before processing SDTM transformation.
4.	Enhanced JOIN_KEY tab for SDTM spec	Feature Enhancement	An optional Join Type has been added to JOIN_KEY to support new "Left Minus Right" operation (only "Inner Join" was supported). The "Left Minus Right" is used to identify records that exist in the Left Source Table but do not in the Right Source Table, and to copy only such records from source to SDTM.
5.	Announcements in English/Japanese on the Login page	Feature Enhancement	The announcements on the Login page are now displayed either in English or Japanese depending on the language setting of a user's web browser.
6.	Desktop Tools V1.1.0 has been bundled	Feature Enhancement	tsClinical Metadata Desktop Tools, which is used for Define-XML and ODM-XML export/import functionality, has been replaced from V1.0.3 to V1.1.0. The new "Has No Data" and "Repeat N" columns introduced in the V1.1.0 have been incorporated into the SDTM spec.

No.	Summary	Type	Description
7.	Error Report (NOT_SUBMITTED) detects Unmapped Common Variables	Bug Fix	The Error Report NOT_SUBMITTED functionality detects source variables that are not mapped to SDTM. The functionality has been updated not to detect Unmapped Common Variables, which are not expected to be mapped. It has also been improved to consider Medidata Rave field suffixes (e.g. _RAW, _STD).
8.	Engine Version not exported into SDTM Spec (Executable)	Bug Fix	Engine Version is the version of the SDTM Automation platform and can be determined by the Built-in Library version. The Engine Version is now exported into the STUDY sheet when a SDTM spec is exported in the Excel (Executable) format so that the SDTM Automation considers it when running SDTM conversion.
9.	Multiple bug fixes to Method Editor	Bug Fix	The multiple bugs of the Method Editor on the SDTM Spec Variable Mapping page. The bug fixes include: <ul style="list-style-type: none"> <li>- Method Name now shows number of parameters (e.g. copy (3), copy (4*))</li> <li>- Appropriate Method Name is selected, considering number of parameters, when the Method Editor is opened to edit current method text.</li> </ul>
10.	Dictionary versions not reflected to Trial Design	Bug Fix	The following properties that appear on the Trial Design Edit page are now reflected to the TS sheet when the Trial Design is exported in the Excel format. <ul style="list-style-type: none"> <li>- NDF-RT/MED-RT Ver.</li> <li>- SNOMED Version</li> <li>- UNII Version</li> </ul>
11.	Standard Unit was required on UNIT page	Bug Fix	The Standard Unit column on the SDTM Spec UNIT page has been changed from required to optional.

## ■ Known Issues, Limitations

No.	Summary	Description
1.	Define-XML 2.1.n will be supported by the next minor upgrade	This version of tsClinical Metadata does not support Define-XML 2.1.n yet, while it is supported by the Desktop Tools V1.1.0. The Define-XML 2.1.n will be supported by the next minor upgrade.