

V2.7.0 Release Note – 03 Dec 2023

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	New Release of Method Library	Feature Enhancement	<p>A new version of Method Library (Library Version 20231203.01, Method Version V20231027.01), which include the following enhancements has been released:</p> <ul style="list-style-type: none"> - The JOIN feature now allows an option to convert Join ID as a new Source ID so that non-join methods such as copy(), toISO8601() can be used for the joined table. - The join(), joinTopic(), lookupConceptJoin(), and lookupConceptJoinNormalized() methods have been deprecated since this library version while joinMultiple() and joinUnique() are still available. - The sv() method now considers time part when deriving SVSTDTC/SVENDTC. - TSVAl in Trial Design - TS now allows count(), min(), max(), and countDistinct() methods.
2.	New Manage Study Metadata Top Page	Feature Enhancement	<p>A brand-new Manage Study Metadata top page has been launched with the following new features:</p> <ul style="list-style-type: none"> - Data specs in projects are toggled (hidden by default and shown by a click). - The View menu groups Properties (formerly Edit), Versions and Action Log - The Update menu groups Properties (formerly Edit), Create New Version and Change Status - The Automation menu groups Auto-Map and Auto-QC (formerly Error Report) - The Compare menu now enables comparison between any versions.
3.	Release of Auto-QC Feature for SDTM Spec Validation	Feature Enhancement	<p>Auto-QC (formerly Error Report) feature has been released with initial 72 SDTM spec validation rules. The report format has been renewed for better readability with colored rows per error level, comprehensive record positions at error, and a list of all rules for reference.</p>
4.	Dynamic Method Validation	Feature Enhancement	<p>Auto-QC feature runs automatically on the Variable Mapping page of SDTM spec so that method errors can be viewed dynamically on the screen.</p>
5.	Exclusion of EDC Records	Feature Enhancement	<p>The EDC_KEYS page of the CRF spec now allows a user to define criteria of EDC records to be excluded from mapping to SDTM.</p>
6.	Debug Feature of SDTM Automation (JOBSCRIPT)	Feature Enhancement	<p>A new JOBSRIPT page in SDTM spec allows a user to stop at a certain step or skip some steps when the spec is run on SDTM Automation. It also allows configuring transformation order of SDTM domains and variables.</p>

No.	Summary	Type	Description
7.	Methods for TSVAl in Trial Design (since Method Version V20231027.01)	Feature Enhancement	The count(), min(), max() and countDistinct() methods can now be entered into the TSVAl column of Trial Design – TS so that the TSVAl is automatically derived from SDTM datasets. This feature is supported since Method Version V20231027.01.
8.	New Join Feature to Create New Source ID (since Method Version V20231027.01)	Feature Enhancement	The JOIN_KEY page in SDTM spec now offers a new feature "Create New Source ID" so that the joined table (Join ID) is treated as a new eDT, for which non-join methods such as copy(), toISO8601() can be used. This feature is supported since Method Version V20231027.01.
9.	Support for Time Variable in SV Domain (since Method Version V20231027.01)	Feature Enhancement	The VISIT_LIST page in SDTM spec now allows a user to define both Date Variable and Time Variable in the DateTime Variables column so that the time part is populated in SVSTDTC/SVENDTC. This feature is supported since Method Version V20231027.01.
10.	Desktop Tools V1.1.3 has been bundled	Feature Enhancement	tsClinical Metadata Desktop Tools, which is used for Define-XML and ODM-XML export/import functionality, has been upgraded from V1.1.0 to V1.1.3.
11.	Mapping Preview (Beta Feature)	Feature Enhancement	This beta feature (pre-release feature for trial) enables a user to simulate how a SDTM dataset is created from a raw table based on the current variable mapping. The feature creates a sample raw table from its spec (i.e. variables and codelist) and runs Python programs that simulate methods in the variable mapping. Note that only limited types of methods are simulated in this version.
12.	Table scrolled to top when Concept Mapping is edited	Bug Fix	The Concept Mapping table was always scrolled to top when the Concept Name was updated. The issue has been fixed.
13.	Multiple length values cause an error when uploaded to SDTM Automation	Bug Fix	Multiple length values (separated with semicolon) in the Variable tab of SDTM spec caused an error when the SDTM spec was uploaded to SDTM Automation. The issue has been fixed.

■ Known Issues, Limitations

No.	Summary	Description
1.	Support for Define-XML 2.1.n is TBD.	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 in future versions.
2.	Release of Method Library for SDTM-IG 3.3 and 3.4 is TBD	SDTM-IG 3.3 and 3.4 standards are already released, but the latest Method Library, which enables automated datasets creation using the SDTM Automation product, is still for SDTM-IG 3.2. A Method Library for SDTM-IG 3.3 is currently under development.