V2.8.0 Release Note – 1 December 2024

■ 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 20241124.01, Method Version V20241124.01) has been released. This is the first version that supports SDTM-IG 3.3, which includes the following enhancements: - Use Cases have been created/assigned for new domains and variables. - Methods for ARMCD/ACTARMCD/ARMNRS have been created/updated to support both SDTM-IG 3.2 and 3.3.
2.	Support for TM Domain in Trial Design	Feature Enhancement	You can now edit/export/import the TM domain in Trial Design when its associated SDTM-IG version is 3.3 or later.
3.	Auto-Map and Auto-QC has been updated for SDTM-IG 3.3	Feature Enhancement	Methods suitable for ARMCD/ACTARMCD are different between SDTM-IG 3.2 and 3.3. Both Auto-Map and Auto-QC have been updated to distinguish suitable methods based on IG version of the SDTM spec.
4.	JOBSCRIPT has been updated for SDTM-IG 3.3	Feature Enhancement	The default JOBSCRIPT (execution order of methods in Variable Mapping) has been updated to support new domains and variables added in SDTM-IG 3.3
5.	Support for Exclusion Variables in EDC_KEYS	Feature Enhancement	You can now define "Exclusion Variables" in the EDC_KEYS tab of a CRF spec that define which EDC records should be excluded from mapping. You were able to define exclusion criteria for EDC key variables before this version.
6.	The refRange() method did not calculate age range correctly when the age is below 10 or above 99.	Bug Fix	The refRange() method calculated age range correctly when both the subject age and the range (min/max age) fall between 10 and 99, but could be incorrect otherwise. The bug has been fixed in this version.

■ 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 3.4 is TBD	SDTM-IG 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 3.3.