V2.7.8 Release Note – 21 September 2024

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	EC-to-EX Exclusion Criteria parameter added to SDTM spec	Feature Enhancement	A new parameter "EC-to-EX Exclusion Criteria", that defines which EC records should be ignored when the EX dataset is derived, has been added to the EXPOSURE tab of the SDTM spec. The parameter is exported to the STUDY sheet. The parameter is effective since the Built-in Library Version 20240701.01 (Engine Version V20240922.01).

■ 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.