

V2.9.0 Release Note – 06 July 2025

■ 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 20250629.01, Method Version V20250622.01), which include the following enhancements has been released: <ul style="list-style-type: none"> - The toxgr() and tox() methods have been created to enable derivation of the --TOXGR/--TOX variables using settings on the TOXGR tab of the SDTM spec. - Configuration options have been added to derive EX from EC. The options allow users to define which records in the EC datasets are "base period" instead of letting SDTM Automation to decide.
2.	Support for Define-XML Terminology	Feature Enhancement	The CDISC Define-XML Terminology is now added to the regular Controlled Terminology updates, starting from Define-XML Terminology 2025-03-28. You can assign Define-XML Terminology to a study SDTM/ADaM spec or a study Analysis Result Metadata. Relevant pick lists shown in the edit page are created based on the Define-XML Terminology.
3.	Updated SDTM/ADaM Spec Edit Pages	Feature Enhancement	The edit pages of SDTM/ADaM specs have been expanded to support new attributes defined in Define-XML V2.1 and to provide independent Comments/Methods definition. <ul style="list-style-type: none"> - (New) Standard tab - (Added) Standard-related attributes on the Dataset, Variable and Codelist tabs - (New) Method tab - (New) Comment tab - (Added) Comment-related attributes on the Study, Dataset, Variable, Value, Dictionary and Codelist tabs - (Added) Method-related attributes on Variable and Value tabs
4.	Default TOXGR Derivation Criteria based on CTCAE V5.0	Feature Enhancement	The new TOXGR tab has been added to the SDTM spec that defines criteria used to derive toxicity grade (i.e. --TOXGR and --TOX variables). The system also provides default derivation criteria from CTCAE V5.0 where the MedDRA SOC is "Investigations".

■ Known Issues, Limitations

No.	Summary	Description
1.	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.