

V2.7.5 Release Note – 14 July 2024

■ 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 20240701.01, Method Version V20240728.01), which includes the following enhancements has been released:</p> <ul style="list-style-type: none"> - Sort algorithms of some methods have been updated so that null records are sorted first then non-null records. The null-first sort algorithm was implemented in V20230401.01, but some methods were not updated accordingly. - When EX is created from EC, records in EC with null ECSTDTC or ECENDTC were excluded from EX. Such behavior has been modified so that records with non-null ECSTDTC and null ECENDTC are reflected to EX.. - When Demographics as Collected (DC) domain is created, the system now creates the SUBJID variable in RELREC, CO and SUPP-- datasets. - The visitnum() method returned a default VISITNUM (e.g. 999) when a single unscheduled visit (a visit identified by a unique combination of TSC_SubjectID/TSC_VisitID/TSC_VisitRepeatKey) has multiple visit dates. The method now returns chronological VISITNUM (e.g. 6.01, 6.02) based on each visit date.
2.	Blank value is now supported in Biomedical Concept	Feature Enhancement	Biomedical Concept with a blank variable value is now supported so that the lookupConcept() method can assign an empty value.
3.	Mapping from source to EX is now supported	Feature Enhancement	EX can now be selected as the mapping target in the Dataset Mapping page. Mapping from source to EX is supported with method libraries on or after 20230625.01.
4.	New "Unscheduled VISITNUM Policy" property added to SDTM spec	Feature Enhancement	<p>The new "Unscheduled VISITNUM Policy" property has been added to the STUDY tab of SDTM spec. The property determines behavior of SDTM Automation in assigning VISITNUM value for unscheduled visits.</p> <ul style="list-style-type: none"> - SVSTDTC-SVENDTC (default): The system identifies a scheduled visit to which an unscheduled visit belongs by SVSTDTC-SVENDTC. The default VISITNUM (e.g. 999) is assigned when multiple scheduled visits are identified. - SVENDTC: The system identifies a scheduled visit to which an unscheduled visit belongs by preceding SVSTDTC. The largest VISITNUM is selected when multiple scheduled visits are identified.

No.	Summary	Type	Description
5.	Run Mode can be selected when exporting SDTM spec in Excel (Executable)	Feature Enhancement	The following Run Mode can be selected when exporting SDTM spec in the Excel (Executable) format to control whether SDTM Automation will run in debug mode. When the debug mode is selected, SDTM Automation will generate working datasets and debug logs.
6.	Use Case is cleared when Method is edited	Feature Enhancement	When method is updated on the Variable Mapping page, then the Use Case will be cleared when the updated method and the Use Case definition is different.
7.	Auto-QC Rule "METHOD-00039: Method Updated" improved	Feature Enhancement	Auto-QC Rule "METHOD-00039: Method Updated" was fired when the current method was not found in any of <i>all</i> use cases. The rule is now fired when the current method is not found in any <i>suggested</i> use cases.
8.	Incorrect Validation Check on Trial Design TI	Bug Fix	Validation checks about uniqueness on the Trial Design - TI page did not take TIVERS into account. The issue has been resolved.

■ 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.