

V2.6.6 Release Note – 23 Apr 2023

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	Support for Multiple Codelists per Standard Variables	Enhancement	SDTM-IG 3.3 started to define multiple codelists per variable (e.g. NCOMPLT and PROTMLST for DSDECOD). The Manage Standards menu now supports multiple codelists. The Create New Data Spec function assigns the first codelist only when a SDTM/ADaM spec is created from a standard.
2.	Support for ADaM Subclasses	Enhancement	ADaM-IG started to support Subclasses such as TIME-TO-EVENT for BDS. The system now supports subclasses in both ADaM standards and specs.
3.	Default TSVCDREF value corrected for FCNTRY	Bug Fix	The system formerly assigned "ISO 3166-1 alpha-3" for the default value of the Trial Summary FCNTRY parameter. The default value has now been changed to "ISO 3166".
4.	Grayed-out Fields are not removed when Data Type/Origin is changed in SDTM/ADaM spec	Bug Fix	Some fields on the Variable tab of a SDTM/ADaM spec are grayed out when the Data Type/Origin field is changed, but the data in such fields were not removed. This issue has been fixed.
5.	Creating second ADaM spec per Study fails	Bug Fix	Creating a second ADaM spec in a study failed due to Duplicated Source ID error. This issue has been fixed.

■ Known Issues, Limitations

No.	Summary	Description
1.	Release of Method Library for SDTM-IG 3.3 and 3.4 is TBD	SDTM-IG 3.3 and 3.4 standards have been released in this version. However, 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.