

V2.4.0 Release Note – 17 Sep 2021

■ Important Note

Supported browsers have been changed since this version as below.

Supported Browsers	<ul style="list-style-type: none"> • Internet Explorer 11 *1 • The latest version of Google Chrome • The latest version of Mozilla Firefox • The latest version of Microsoft Edge <p>*1: Support for Internet Explorer 11 (IE11) will end in pace with the retirement of IE11 (anticipated on June 15, 2022). Also, feature enhancements since this version will not support IE11.</p>
Minimum Screen Resolution	1024 x 768

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	Trial Design Wizard	Feature Enhancement	This version now offers the following options to create Trial Design: (1) Create Trial Design using Graphical Editor (2) Create Trial Design from Excel File (3) Create Blank Trial Design
2.	Updated Trial Design pages	Feature Enhancement	The following features have been added to Trial Design: - TE-TA Fig. Graphical representation of Trial Elements/Arms - TV Fig. Graphical representation of Trial Visits - TI New "Original IETEST" field and Preview functionality to support Inclusion/Exclusion Criteria in both original and submission formats.
3.	Standard Biomedical Concepts	Feature Enhancement	AutoMap, Study Biomedical Concept and Study SDTM Concept Mapping now have access to Biomedical Concepts created from SDTM-CT.
4.	Dataset Summary and Tests-Units Summary	Feature Enhancement	The "Excel (Archive)" format of SDTM spec export now generates the following summary reports: - Dataset Summary Report Summary of mapping patterns derived from Dataset, Variable, Concept and Codelist Mappings. - Summary of Tests and Units List of all tests and units in the Findings domain excluding IE.
5.	New Page for Dataset Mapping	Feature Enhancement	This version now provides a new Dataset Mapping page for better usability. The prior version provided the similar functionality on the Dataset page.

No.	Summary	Type	Description
6.	Enhanced Concept Mapping Page	Feature Enhancement	The Concept Mapping page has been updated to enable the followings: <ul style="list-style-type: none"> - Search from Standard Biomedical Concepts - Save selected Standard Biomedical Concepts to Study Biomedical Concepts.
7.	Enhanced AutoMap	Feature Enhancement	This version now offers enhanced AutoMap feature with the following functionality: <ul style="list-style-type: none"> - Mapping from eDT to SDTM - Automated generation of Codelists and Biomedical Concepts - Automatic join of non-topic tables
8.	Enhanced Concept Mapping Capability	Feature Enhancement	This version provides "Abstract Methods" to enable simple Concept Mappings from various source tables (e.g. Normalized/Denormalized/Join)
9.	Variable/Value Level Metadata from Mappings for Define-XML	Feature Enhancement	This version now provides "Update from Mapping" functionality, which updates variable and value level metadata of SDTM spec based on mapping information.
10.	Method and Condition Tabs to CRF Spec	Feature Enhancement	This version now provides new pages for Method and Condition for CRF Spec (i.e. derivation formula and logical checks as defined in the ODM specification).
11.	Minor Update to eDT Spec	Feature Enhancement	The following updates have been implemented to eDT spec: <ul style="list-style-type: none"> - New eDT Type "KeyCode Table" ("Treatment Assignment" has been deprecated) - New field "Column Label"
12.	Minor Update to Codelist Mapping	Feature Enhancement	This version now generates value lists from SDTM-CT on the Codelist Mapping tab when no values are found in the Codelist tab, and saves the values to Codelist when they are from SDTM-CT.
13.	More Extra Variables to Variable Mapping	Feature Enhancement	This version now supports Extra Variables for Japanese MedDRA Coding Variables (e.g. AELLT_J) and those for ACTARMCD (e.g. AARMCD01).
14.	New Release of Method Library	Feature Enhancement	New version of Method Library (Library Version 20210906.01, Method Version V20210604.01), which include enhancements #7 and #11 have been released.
15.	Fields added in V2.3.0 not imported from Excel	Bug Fix	The issue that the new fields added in V2.3.0 (i.e. Source and Evaluator) are not imported from Excel has now been fixed.
16.	Blank dataset created by "Add ADaM Dataset" with ADaM-IG 1.1	Bug Fix	This version creates a new dataset from template, while the prior version created blank dataset, when adding a new dataset to a standard or data spec based on ADaM-IG 1.1.
17.	Inappropriate Core value of Custom Dataset to SDTM/ADaM Data Spec	Bug Fix	The issue that "Perm" is assigned to all variables of custom datasets has now been fixed.

No.	Summary	Type	Description
18.	Default ADaM variable name in Study ADaM Spec is displayed as read-only	Bug Fix	The issue that default ADaM variable names in Study ADaM spec is displayed as read-only has now been fixed.
19.	Inappropriate validation check at Standard CRF Import	Bug Fix	An inappropriate check that validates one-to-one relationship between Variable and Codelist has been removed.
20.	Inappropriate validation check at Study SDTM Spec Import	Bug Fix	An inappropriate check that detects COVAL and RELREC in the MAPPING_VARIABLE as inconsistency with the VARIABLE sheet has been removed.

■ Known Issues, Limitations

No.	Summary	Description
1.	Slow Show/Hide operation with Internet Explorer 11	The Show/Hide Details button works slow with Internet Explorer 11.