V2.5.0 Release Note – 27 Sep 2022

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	Support for Multi-Factor Authentication	Feature Enhancement	This version now supports Multi-Factor Authentication (MFA) that conforms to NIST Authenticator Assurance Level 2 (AAL2). System administrator can now choose for each user whether to enable additional authentication step (One-Time Password using Google/Microsoft Authenticator installed on the user's smart phone) in addition to password authentication.
2.	Enhancement of Login History Page	Feature Enhancement	With the support of MFA, the Login History page now logs authentication types (password or OTP). The system temporarily locks a user if the user fails OTP authentication too frequently. Also, the Login History page now logs authentication attempt against a user ID that does not exist in the tenant.
3.	Email Notification at Security Events	Feature Enhancement	The system now notifies a user via email with a valid email address when the user account is temporarily locked due to too frequent authentication failures.
4.	Enhanced Versions View and VERSIONS Sheet in Excel Export	Feature Enhancement	View Versions functionality (of Standard, Terminology, ARM and Study Data Spec) now displays the following information: - Creation Date - Created By - Approval Date - Approved By Also, the VERSIONS sheet that contains the same information as the Versions view has been added into Excel export.
5.	Support for "Near-SDTM" Data Spec	Feature Enhancement	This version now supports "Near-SDTM" as the new study data spec type (i.e. CRF, eDT, SDTM and ADaM). "Near-SDTM" is data structure of clinical operational database where EDC and eDT datasets are imported. It is like SDTM structure with additional operational data (SDTM+) and without derived SDTM variables (SDTM-).

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No.	Summary	Type	Description
6.	Enhanced Variable Mapping Page	Feature Enhancement	The following features have been added on the Variable Mapping page to facilitate SDTM automation: (1) Source Topic Pair Variable: The new "Source Topic Pair Variable" keyword in the Source Variable enables a user to map different source variables depending on each Source Topic Variable. (2) Find Use Case: A list of use cases were provided in a dropdown list in former versions. This version now allows a user to search use cases from a list of all use cases.
7.	Enhanced VISIT_LIST Page	Feature Enhancement	The VISIT_LIST page now allows two Display Mode, Source and SDTM, to facilitate SDTM automation. The Source mode is the functionality provided in former versions. The new SDTM mode helps to simplify mapping of time-points
8.	Dataset Sources in Dataset Page and DATASET Sheet in Excel Export	Feature Enhancement	The Dataset page and Excel export of the Study SDTM/ADaM data spec now displays source tables referenced from variable mappings of the dataset.
9.	New Release of Method Library	Feature Enhancement	A new version of Method Library (Library Version 20220225.01, Method Version V20220225.01), which include the following enhancements has been released: - New method coeval() to derive COEVAL - New method svupdes() to derive SVUPDES - New method taetord() to derive TAETORD - New method dateGroup() to simplify derivation of RFPENDTC - Updated method lookupDomainREGEX() to enable complex derivation of RFENDTC - Updated method epoch() to take pre-dose timepoint into account when deriving EPOCH - Updated method lobxfl() to take pre-dose timepoint into account when deriving –BLFL - No Explanation is associated with any Use Case so that the Explanation column in the Variable Mapping can be fully used as an instruction or a comment.
10.	Minor Update to Study Tab of SDTM Data Spec	Feature Enhancement	The Study tab of SDTM data spec now provides the following parameters referenced from the new method library #9: - Pre-dose Variable - Pre-dose Value - Treatment EPOCH Value
11.	False-Positive Errors in Error Report	Bug Fix	The following false-positive errors detected as METHOD_ERRORS in Error Report have been fixed: - IncorrectParameterType error when an extra variable is one of method parameters - IncorrectSdtmVariable error when comment() is used for COVALn

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No.	Summary	Type	Description
12.	Analysis Variables in Analysis Datasets tab of ARM not displayed properly	Bug Fix	Analysis Variables entered by free text (i.e. a variable not included in the referenced ADaM datasets) were not displayed when the page was reloaded. The issue has been fixed in this version.
13.	AutoMap fails to assign _RAW or _STD variables in Concept Mapping when the CRF spec is for Medidata Rave	Bug Fix	When the source CRF spec is for Medidata Rave, then the AutoMap should assign _RAW or _STD variables as Source Variable in Concept Mapping. The issue has been fixed in this version.
14.	Controlled Terminology in My SDTM Standard is not reflected to SDTM spec	Bug Fix	Controlled Terminology (i.e. codelist reference from variable) in My SDTM standard was not reflected to SDTM spec when it was created. The issue has been fixed in this version.
15.	Version Comment is copied to new version	Bug Fix	Version Comment of the current version, which should not be copied to the new version, was copied when the new version was created. The issue has been fixed in this version.
16.	Incorrect highlight in Compare reports when no Order difference is found	Bug Fix	Compare reports incorrectly highlighted the last column in each sheet when no Order difference was found. The issue has been fixed in this version.
17.	Codelist ID of eDT Column fails to be updated	Bug Fix	The Codelist ID on the Column page of eDT Spec failed to be updated when saving. The issue has been fixed in this version.

■ 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.

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