

V2.0.0 Release Note – 30 September 2019

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	Business Administrator and System Administrator roles	Feature Enhancement	Former Administrator role has now been split into Business Administrator and System Administrator roles. Business Administrator is a super user over business data while System Administrator oversees user access.
2.	CDISC Standards and Terminologies maintained by the system	Feature Enhancement	In previous versions, each tenant needed to maintain CDISC standards and terminologies. From this version, the system maintains all CDISC-published standards and terminologies, including adding new terminology releases. Business Administrator still keeps governance over the CDISC standards and terminologies by maintaining the "Is Published" property.
3.	Status and version control support	Feature Enhancement	The system now provides version control feature and manages status (Draft, Approved, Obsolete and Suspended). All metadata are now created as the Draft status and becomes protected when promoted to the Approved status. A new Draft version can be created based on the Approved version.
4.	Upgraded terminology management features	Feature Enhancement	Terminology now has a "Base Terminology" concept, a CDISC-published terminology on which a user-defined terminology is based. A user-defined terminology can be created with ranges over multiple Base Terminology versions, and its Base Terminology can be easily switched when used for a specific study. The system also provides helpful features to manage deprecated codelist items for each Base Terminology version.
5.	Upgraded Analysis Results Metadata (ARM) features	Feature Enhancement	The system now provides features to create Analysis Results Metadata, which conforms to ARM for Define-XML, at the Standard level, so that it can be utilized for each study. The system now assumes creating an ADaM spec and an ARM separately at the study level and combining together when exporting out of the system.
6.	Support for Trial Design	Feature Enhancement	The system now provides features to create Trial Design that conforms to SDTMIG and to export in the Excel format.
7.	Support for eDT Spec	Feature Enhancement	The system now provides features to create a spec for Electronic Data Transfer (eDT) at the study level. The eDT spec supported by the system is a text file in a table format.

No.	Summary	Type	Description
8.	Enhanced SDTM Spec to enable SDTM Automation	Feature Enhancement	The system now provides SDTM automation features by collaborating with an optional SDTM transformation engine that transforms source data into SDTM datasets. To achieve the SDTM automation, the system now provides enhanced SDTM spec features including Method Library, Dataset Mapping, Variable Mapping, Codelist Mapping and Concept Mapping.
9.	Support for Biomedical Concept	Feature Enhancement	Biomedical Concept is a set of SDTM/ADaM variable-value pairs that represent a specific clinical study event or finding. The system now provides Biomedical Concept features in consideration of SDTM automation.
10.	Enhanced Excel Import	Feature Enhancement	From this version, excel import features (importing metadata from an external Excel file) now identifies columns by column name, rather than by column number in previous versions. The system also provides richer import validation features.
11.	Comparison Report in Excel	Feature Enhancement	All metadata comparison report in this version is now downloaded as an Excel file, while the former versions displayed a comparison report on the screen.

■ Deprecated Features

No.	Deprecated Feature	Successor Features	Note
1.	Copy Standard	Create New Standard Create New Version	-
2.	Import Standard - RDF	N/A	Importing CDISC standards are now maintained by Fujitsu.
3.	Import Standard - Excel	Create New Standard Create New Version	-
4.	Extend Standard	Create New Standard	-
5.	Copy Terminology	Create New Terminology Create New Version	-
6.	Add Bookmark Migrate Bookmark	Create New Terminology Create New Version	The new terminology features combine former Terminology and Bookmark concepts.
7.	Import Terminology - ODM	N/A	Importing CDISC terminologies are now maintained by Fujitsu.
8.	Import Terminology - Excel	Create New Terminology Create New Version	The successor features are now being developed to release soon in V2.0.x.
9.	Copy Data Spec Add Data Spec	Create New Data Spec Create New Version	-
10.	Import Data Spec - Excel	Create New Data Spec Create New Version	-
11.	Import Data Spec - define.xml	Create New Data Spec Create New Version	The successor features are now being developed to release soon in V2.0.x.
12.	Archive	Change Status	-
13.	Map	AutoMap Report AutoMap	The successor features are planned to release in V2.1.
14.	Manage Master Data	N/A	The feature is partly covered by Method Library features.

■ Known Issues, Limitations

No.	Summary	Description
1.	Terminology Import feature is not yet included in this release.	Terminology Import feature is now being developed to release soon in V2.0.x.
2.	Define-XML Export/Import features are not yet included in this release.	Define-XML Export/Import features are now being developed to release soon in V2.0.x.
3.	ODM-XML Export feature is not yet included in this release.	ODM-XML Export feature is now being developed to release soon in V2.0.x.