

V2.1.0 Release Note – 19 Jun 2020

■ Feature Enhancements and Bug Fixes

No.	Summary	Type	Description
1.	First release of AutoMap	Feature Enhancement	AutoMap automates mapping from CRF and eDT specs to a designated SDTM spec using knowledge base and natural language processing technology. A user can download the AutoMap result, or save the result on to the SDTM spec.
2.	First release of Desktop Tools	Feature Enhancement	Desktop Tools is now shipped with tsClinical Metadata and available from the Content Library page. It is a tool set that runs on your PC to create CRF specs, eDT specs, ODM-XML and Define-XML and enables smooth data integration with other systems.
3.	NOT_SUBMITTED in Error Report	Feature Enhancement	The Error Report functionality now generates a NOT_SUBMITTED sheet to display which fields in CRF and eDT specs are not mapped to a designated SDTM spec.
4.	Overall GUI enhancements of a table layout in Manage Study Metadata	Feature Enhancement	Most pages of a table layout under the Manage Study Metadata menu have now been rebuilt with more user-friendly design such as; <ul style="list-style-type: none"> - Show/Hide Details (only important fields are displayed by default) - Move cursor using cursor keys (←↑→↓) - A long text field is automatically spread when focused.
5.	Content Library menu	Feature Enhancement	A new Content Library menu has been added where a user can download documentation and tools (e.g. Desktop Tools)
6.	Method Editor	Feature Enhancement	Methods in the Variable Mapping page can now be edited using Method Editor where a user is assisted with method documentation and conformance check.
7.	Improved Dataset Mapping GUI	Feature Enhancement	Multiple topic variables can now be grouped into one Mapping Group to reduce variable mapping effort when the topic variables can be handled with the same variable mapping (while codelist and concept mappings can be different).
8.	SDTM Spec extensions	Feature Enhancement	A SDTM spec is now extended to assist complex data transformation definitions; <p>-----</p> <p><u>JOIN_KEY</u>: Define how to concatenate multiple source tables <u>JOIN_KEY_MAP</u>: Define mapping of key values in JOIN_KEY <u>VISIT_LIST</u>: Define mapping between visits in source data and trial visits in TV <u>EXPOSURE</u>: Define derivation from collected exposure <u>ARM_MAP</u>: Define mapping between randomization tables and trial arms in TA <u>REF_RANGE</u>: Define lab reference ranges <u>UNIT</u>: Define original to standard unit conversion rules <u>RELREC</u>: Define dataset-level RELREC records</p>

No.	Summary	Type	Description
9.	Element Start/End Rules moved from TE to TA	Feature Enhancement	Trial Element Start/End Rules that assists derivation of the SE dataset have now moved from TE to TA.
10.	ControlType, IsLog, and Derived From in CRF Field	Feature Enhancement	ControlType, IsLog, and Derived From columns have been added to the Field page of a CRF spec to support transformation from and annotated CRF of Medidata Rave EDC.
11.	Enhanced CRF Study page	Feature Enhancement	New fields have been added to the Study page of a CRF spec to support transformation from datasets in text format.
12.	Addition of EDC_KEYS to CRF	Feature Enhancement	New EDC_KEYS page has been added where dataset keys are defined to support transformation from the datasets in text format.
13.	Enhanced SDTM Study page	Feature Enhancement	New fields have been added to the Study page of a SDTM spec to allow more flexibility in SDTM transformation.
14.	40 character limit when creating SDTM/ADaM specs from standards	Feature Enhancement	The system now cut variable label by the 40th character when creating a SDTM spec from SDTM-IG. The system also validates 40 character limit when entered on GUI or imported from an external file.
15.	Variable Core in SDTM Field	Feature Enhancement	Variable Core (e.g. Req, Exp, Perm) is now displayed on the SDTM Variable page, and a variable with Req or Exp cannot be deleted.

■ 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.
2.	Some pages are still in the traditional table format	Some pages in the Manage Study Metadata menu are still in the traditional table format (i.e. before the #4 enhancement). Such pages will be enhanced in the upcoming minor versions.