

SDTM Checker

Fact Sheet

SDTM Checker is a validated, stand-alone SAS® program which covers SDTM checks, allows for integration of additional user checks and delivers results as text files or SAS datasets for post-processing.

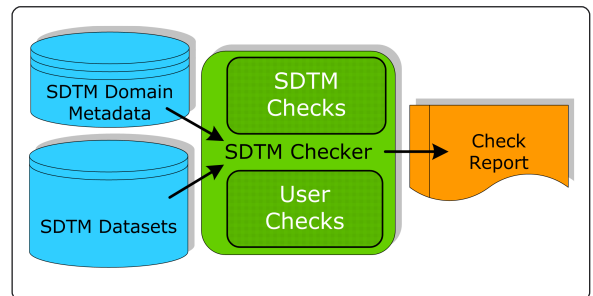
Entimo's SDTM Checker validates clinical data against metadata, inspects structure and data consistency and controls compliance with CDISC SDTM.

SDTM Domain Metadata

Entimo provides a full set of SDTM domain templates. The standard domain definitions can be used at once for data quality checks or easily adjusted to incorporate sponsor-specific (SDTM+) data models.

SDTM Datasets

SDTM domain datasets to be checked are comfortably specified as program parameters. Once defined, the parameter sets can be used for repeated runs with no additional effort.



Check Rules

A wide spectrum of built-in checks includes existence and consistency checks of required and expected data elements, data format and usage of controlled terminology. Check rules can be easily extended and updated along with model changes (e.g. new SDTM versions).

The user is able to integrate customer specific checks. An additional check program is addressed via parameter and is automatically executed during SDTM Checker's runs. Results of additional checks are included into the main check report.

Check Report

Identified quality issues are reported according to severity classification (high–medium–low). Thus the issue list can be easily communicated to the sponsor. The check report is stored as a SAS dataset for post-processing or as a text file.

entimICE DARE Integration

When running the SDTM Checker within Entimo's Integrated Clinical Environment (entimICE®), you benefit from:

- Drag-and-drop GUI support for easy check execution and parameter definition
- Repeatable and reproducible runs
- Full-fledged traceability of program executions

3 reasons for Entimo's SDTM Checker:



1. Validated tool:

SDTM Checker passed extensive and documented validation and guarantees expected results. No additional validation packages are required.



2. Quality control follows your processes:

Stand-alone SAS program allows mapping specialists to independently perform data validation, also on SAS datasets. SDTM Checker can be integrated into your workflow and helps automate validation tasks.



3. Comprehensive and extendible:

Standard conformance checks can be easily extended and enhanced with user-specific checks.