

Control quality of your data!

Mission

Entimo's SDTM Checker and ADaM Checker are validated macro solutions which verify compliance of clinical data with CDISC SDTM and ADaM. These tools inspect structure, controlled terminology and value level metadata, run officially published and additional checks and provide detailed reports including result statistics. Driven by metadata and configurable, they easily support standard and custom domains as well as integration of user defined checks. Detailed test results are presented in different formats for effortless analysis.

Benefits of Entimo's Check Tools

1. Validated tools for proven results.
2. Simple use with no cumbersome installation.
3. Early issue detection - no define.xml required.
4. Extendible domains, standard and user checks.

Check Rules

Running directly on SAS datasets, the checkers allow data validation very early in the process. Intra-domain, cross-domain and cross-model checks are executed as far as possible from the very first available domain thus supporting prompt QC. The wide spectrum of built-in checks covers not only all officially published, but also includes many additional checks:

- Consistency checks of required and expected data elements
- Checks of data formats, controlled terminology and against external dictionaries
- SDTM 3.1.1/3.1.2 checks including cross-domain checks
- Numerous value level checks and checks of supplemental qualifiers
- Current ADaM validation rules including SDTM-related checks

Users are able to incorporate custom data models into data checks. The delivered standard structure definitions need to be adjusted to reflect near-SDTM or any custom structure. The changed structure definitions are simply used as reference in check runs in this case. Standard conformance checks may be enhanced with user-defined checks: an additional call program for user checks is addressed via a dedicated parameter and is automatically executed during the checkers' runs. Results of additional checks are included in the main check report.

no	section	domain	message	Filter	result	severity	userid
3	Details	DM	OK: Value for DOMAIN is consistent (DM) dataset(s) DM column(s) diverse		result = not ok		entjod01
3	Details	DM	OK: If armcd equals SCRNFIL then arm is equal Screen Failure and vice versa	Criterion dialog	result != not ok		entjod01
3	Details	DM	OK: Start date is less than or equal to end date dataset(s) DM column(s) RFSTDT RFENDTC		IR5101 ok HIGH		entjod01
3	Details	DM	WARNING: Invalid code (dataset(s) DM column(s) ARM value(s) Placebo row 1)		IR5136 not ok LOW		entjod01
3	Details	DM	WARNING: Invalid code (dataset(s) DM column(s) ARMCD value(s) Pbo row 1)		IR5136 not ok LOW		entjod01
3	Details	DM	WARNING: Invalid code (dataset(s) DM column(s) ARM value(s) Placebo row 2)		IR5136 not ok LOW		entjod01
3	Details	DM	WARNING: Invalid code (dataset(s) DM column(s) ARMCD value(s) Pbo row 2)		IR5136 not ok LOW		entjod01

Results

Detailed reports provide an overview of checked domains with user and time stamps, links to used controlled terminology, check details with messages, and statistics. Identified quality issues are reported according to severity classification (high-medium-low or user defined). One glance at the statistics section is enough to assess check results: detailed statistics include the results of standard and user checks per domain as well as check summaries. Optionally, test results may be presented as text report or SAS datasets – a comfortable feature which allows easy sorting and filtering of messages, severities and other test results.