

Short introduction to OpenCDISC Version 1.5

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What is OpenCDISC Validator?

- ✓ OpenCDISC Validator is an open source, easy to use, and commercial-quality tool for ensuring clinical data compliance with CDISC standards, including SDTM, ADaM, SEND, Define.xml, and others
- ✓ Open source & free
- ✓ Enterprise version also available
- ✓ Also used by the FDA
<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

Usage

- ✓ Can be used with command line
[http://www.phusewiki.org/wiki/index.php?title=Let SAS handle your CDISC compliance check: automating OpenCDISC Validator in SAS](http://www.phusewiki.org/wiki/index.php?title=Let_SAS_handle_your_CDISC_compliance_check:_automating_OpenCDISC_Validator_in_SAS)
- ✓ Or with Graphical User Interface

Usage

OpenCDISC Validator

File Help

What would you like to do? Validate Data Generate Define.xml

Standard: SDTM

Source Format: SAS® Transport (XPORT)

Source Data:

Browse
Remove
Clear

You can select multiple files or folders as sources

Configuration: config-sdtm-3.1.3.xml

Define.xml:

Browse

Optional

Report Format: Excel [Report Settings](#) **CDISC CT:** 2014-03-28 **MedDRA:** 17.0

Progress:

Waiting to begin.

Start Stop

Results

✓ Excel workbook containin 4 sheets

- Dataset Summary:

| Processed Sources | | | | | | | |
|-------------------|-------------------------|---------------|--------|---------|--------|----------|---------|
| Domain | Label | Class | Source | Records | Errors | Warnings | Notices |
| GLOBAL | Global Metadata | -- | -- | -- | 0 | 0 | 0 |
| AE | Adverse Events | Events | ae.xpt | 2067 | 56 | 3224 | 8 |
| CM | Concomitant Medications | Interventions | cm.xpt | 4991 | 20 | 1480 | 656 |

- Issue Summary:

| Issue Summary | | | | |
|---------------|------------------------|---|----------|-------|
| Source | Rule ID | Message | Severity | Found |
| AE | | | | |
| | CT0001 | Value for AEACN not found in (ACN) CT codelist | Error | 13 |
| | SD0002 | NULL value in AEDECOD variable marked as Required | Error | 12 |
| | SD0002 | NULL value in AETERM variable marked as Required | Error | 3 |

- Details:

| Domain | Record | Count | Variables | Values | Rule ID | Message | Category | Severity |
|--------|--------|-------|-----------|-------------|------------------------|---|-------------|-------------|
| AE | | 13 | AEACN | MULTIPLE | CT0001 | Value for AEACN not found in (ACN) CT codelist | Terminology | Error |
| AE | | 1 | AEDECOD | Candidiasis | SD0008 | Value for AEDECOD not found in MedDRA dictionary | Terminology | Error |
| AE | | | AEREFID | | SD1078 | Permissible variable with missing value for all records | Presence | Information |

- Rules:

| Rule ID | Message | Description | Category | Severity |
|---------|--|---|-------------|----------|
| CT0001 | Value for --ACN not found in (ACN) CT codelist | Action Taken with Study Treatment (--ACN) variable values must be populated with terms found in 'Action Taken with Study Treatment' (C66767) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist. | Terminology | Error |
| CT0002 | Value for AESEV not found in (AESEV) CT codelist | Severity/Intensity (AESEV) variable values must be populated with terms found in 'Severity/Intensity Scale for Adverse Events' (C66769) CDISC controlled terminology codelist. New values cannot be added into the CDISC CT non-extensible codelist. | Terminology | Error |

What's new in Version 1.5

- ✓ Validation against SDTM 1.4 model and SDTMIG v3.2
- ✓ Validation of Define-XML v2.0
- ✓ Support for Dataset-XML format
- ✓ Updated SEND config for FDA compliance
- ✓ Various bug fixes and minor engine enhancements. Please refer to the [changelog](#) for details.
- ✓ Various updates to SDTM 3.1.3, 3.1.2, 3.1.1, and SEND 3.0 configs. For a complete list of validation rule changes please refer to the [release notes](#).

Facts on Version 1.5

- ✓ Identification of ADaM Class not working correctly
 - even if define.xml is provided
 - e.g. BDS checks are run on ADAE
- ✓ Uses only SDTM CT for checks against C-Codes used in define.xml 2.0
 - ADaM CT C-Codes used in define.xml will be reported as errors
- ✓ For support also use the Forum:
<http://www.opencdisc.org/forums/sdtm>
- ✓ Larger update expected for 2014

Questions?

