# CDISC - Resources

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## CDISC Primer
- Guiding Principles
Development of open-source software for the global clinical research community to test study data for conformance to CDISC standards as well as to regulatory and sponsor-specific conformance rule sets.
Why

• Create a set of unambiguous, executable Conformance Rules for each standard
• Ensure consistency across Conformance Rule implementations
• Expedite availability of Conformance Rules for new standards
• Create Rules vetted by the CDISC standard development teams
• Develop an open-source engine that serves as a Reference Implementation
• Publish rules in CDISC library
• Release of open-source engine under COSA
MVP Engine

• Presentation of the CORE Minimum Viable Product (MVP) Engine early evaluation version on CDISC EU Interchange 2022
• The MVP Engine was previously available via the CORE web page
• Provided with a basic user interface (UI) to allow users to quickly and easily run the Engine to provide early feedback on the Engine functionality to the CORE team
View My Studies
View My Studies – Study Details

CDISC PILOT01

Study Details
- Study Start Date: 2012-10-06
- Therapeutic Area: Alzheimer’s Disease
- Phase: II
- Sponsors: CDISC

Study Title: Safety and Efficacy of Zanomeline in Patients with Mild to Moderate Alzheimer’s Disease

Data Bundles
- Data Bundle: Issues
  - Last validation date: 2022-04-22T19:32:09
  - Validate

- Data Bundle: Clean Data
  - Last validation date: 2022-04-14T15:17:56
  - Validate
### CDISC Open Rules Engine

#### View My Studies – View Details

**Datasets**

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<thead>
<tr>
<th>Dataset</th>
<th>Label</th>
<th># Records</th>
<th>Size</th>
<th>Modified Date</th>
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View My Studies – View Details
Conformance Validator

Choose Datasets

Datasets

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Conformance Validator
Validation
## Issue Reporting

### Issue Summary

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<tr>
<th>Dataset</th>
<th>Rule ID</th>
<th>Error Message</th>
<th>Severity</th>
<th># Issues</th>
<th>Explanation</th>
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<tr>
<td>AE</td>
<td>CDISC.SDTMIG.CG0041</td>
<td>At least one of the Seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE) = 'Y', but AESER = 'N' or empty.</td>
<td>Error</td>
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<td>If AESER = 'N' then none of the seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE) could be equal to 'Y'.</td>
<td>Warning</td>
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<tr>
<td>AE</td>
<td>CDISC.SDTMIG.CG0050</td>
<td>AEDECOD should be populated when AEPTOD is populated</td>
<td>Error</td>
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<td>AE</td>
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<td>AESCONG is completed, but not equal to 'N' or 'Y'</td>
<td>Error</td>
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<td>This Issue needs to be resolved</td>
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### Issue Reporting

#### CDISC PILOT01 / Issues / 2022-04-24T14:58:51

**Issue Details**

#### Issue Summary

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<td>FTTPTREF is empty and FTELTM is not empty</td>
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<tr>
<td>CDISC:SDTM10:0.500008</td>
<td>FTTPTREF is empty and FTELTM is not empty</td>
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<td>FTTPTREF is empty and FTELTM is not empty</td>
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<td>CDISC:SDTM10:0.500009</td>
<td>EPOCH is not in TA:EPOCH</td>
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<table>
<thead>
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<th>Dataset</th>
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<th>Record</th>
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<td>FTELTM, FTTPTREF</td>
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<td>PTSDM</td>
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<tr>
<td>Error</td>
<td>FT</td>
<td>CDISC003</td>
<td>960</td>
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<td>FTELTM, FTTPTREF</td>
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<td>Error</td>
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<td>3</td>
<td>EPOCH</td>
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Issue Reporting

CDISC Open Rules Engine

Dashboard / View My Studies / View details / Report details

CDISCPILOT01 / Issues / 2022-04-24T14:58:51

Issue Summary Issue Details Rules Reports

Search

Rule ID: Message
CDISC.SD/DM.CD00067 The date portion of -DTC is not complete date or the date portion of DM.RFTDTOTC is not complete date but -DY is not empty
CDISC.SD/DM.CD00068 --TPTREF is empty and --ELTM is not empty
CDISC.SD/DM.CD00069 EPOCH is not in TA EPOCH
CDISC.SD/DM.CG00026 --RFTDTC is populated when --TPTREF is null

Status:
- Success
- Success
- Success
- Skipped
# View My Studies – View Details

## CDISC Pilot01 / Issues

<table>
<thead>
<tr>
<th>Report</th>
<th>Validation Date</th>
<th># Rejects</th>
<th># Errors</th>
<th># Warnings</th>
<th># Notices</th>
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<tbody>
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<td>0</td>
<td>62</td>
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## Issue Reporting

<table>
<thead>
<tr>
<th>A</th>
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<tr>
<td>Study</td>
<td>CDISCPILOT01</td>
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<tr>
<td>Bundle</td>
<td>Issues</td>
</tr>
<tr>
<td>Total Runtime</td>
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<td>Transaction ID</td>
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**Study Details**

- Therapeutic Area: Alzheimer's Disease
- Phase: II
- Client: CDISC
- Study Start Date: 2012-10-06

**Bundle Details**

- Standard Version: SDTM
- CT Version: V3.1
- Define-XML Version: 2.1
- UNII Version: Not configured
- Med-RX Version: Not configured
- MedDRA Version: Not configured
- WHODRUGS Version: Not configured
- SNOMED Version: Not configured
The CORE Engine Reference Implementation on GitHub is an advancement over the CORE Minimum Viable Product (MVP) Engine early evaluation version. The GitHub-based Engine is updated to process additional Rule syntax (YAML) engaged to handle new processing conditions that were encountered as the CORE team developed additional Rules. The GitHub-based Engine is provided with a command line interface (CLI).
CORE on GitHub

Overview  Planning and Status  Program Governance  Participate  Presentations  FAQ  CORE on GitHub

Latest page content update: 01 Mar 2023

CORE Engine Reference Implementation in GitHub

The CORE Engine Reference Implementation is the current version of the Engine. The CORE Engine Reference Implementation has been tried in the environment with its provision on GitHub. The GitHub-based Engine is:

- Provided as open source with the permissive MIT license
- Registered with the CDISC Open-Source Alliance (COSA)
- Available to users for free
- Provided with a command line interface (CLI)
- Accessed at the GitHub CDISC-rules-engine repository, including special instructions in the Readme file
CORE on GitHub

cdisc-org / cdisc-rules-engine

- main
- 60 branches
- 49 tags

- nhaydel Update version.py
- .github
- cdisc_rules_engine
- Rule schema updates (#246)

- README.md

cdisc-rules-engine

Open source offering of the cdisc rules engine
Thank you!

Questions?

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