



30. CDISC DACH User Network Meeting

Introduction to CORE – a COSA project

14-March-2023



www.mainanalytics.de

CDISC - Resources



- New to CDISC
- Standards
- Education
- Resources**
- Events
- Membership
- Members Only

News

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Global

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- Africa
- Asia
- Australia
- Europe

Translations

- Chinese
- Japanese

Stakeholders

- Global Regulatory Requirements
- Cases for Clear Data
- Partner Organizations
- 3C
- User Networks

Volunteering at CDISC

- Volunteer Spotlight
- Become a Volunteer

Services

- ODM Certified Products
- ODM Benefits and Rates
- Become ODM Certified

COSA

- CORE**
- OAK

TMF Reference Model

- TMF Reference Model website
- Become a TMF Volunteer

Knowledge Base

- Articles
- Examples Collection
- Known Issues
- eCRF Portal

CDISC Primer

Guiding Principles

CORE – CDISC Open Rules Engine

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CORE

Overview

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CORE on GitHub



Latest page content update: 24 Nov 2022

Page Note:

The CORE project originated as a traditional CDISC project with planning and volunteer/collaborator recruitment during spring & summer 2021 and formal kickoff in Sept 2021. During summer 2022, CDISC transitioned CORE development to an open-source framework. This page (tab) describes the project goals, objectives, and high-level roadmap; Please see the Program Governance page (tab) for description of the open-source governance framework. Please see the Planning & Status page (tab) for the latest CORE activity, which is now guided by the open-source CORE Roadmap Board.

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

CDISC CORE



CDISC Open Rules Engine

- Dashboard
- Conformance Validator
- Rule Editor
- Plugin
- View My Studies
- Manage My Rule Sets
- Help

Welcome to CDISC CORE



Conformance Validator

Validate your study with the most recent Conformance rules from the CDISC Library



Rule Editor

Create your own rules with the Rule Editor



Plugin

Create your own Plugin and use it within CORE

Recent Studies

[Refresh](#) [See all >](#)

Study	Data Bundle	Standard	Last Validation Date ↓
CDISCPILLOT01	Issues	SDTM	2022-04-22T19:32:09
CDISC-TEST	Original Data	SDTM	2022-04-20T08:33:23
CDISCPILLOT01	Clean Data	SDTM	2022-04-14T15:17:56

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Resources

[> User Manual](#)



View My Studies

Dashboard / View My Studies

View My Studies

Search

^ Collapse All + Add Dictionaries + Add Study

CDISCPLOT01	Therapeutic area: Alzheimer's Disease	Phase II	Client: CDISC	+ Add Bundle	View	Delete ^
-------------	---------------------------------------	----------	---------------	--------------	-------------	----------

Data Bundle **Issues** SDTM

Last validation date: 2022-04-22T19:32:09

Validate

Data Bundle **Clean Data** SDTM

Last validation date: 2022-04-14T15:17:56

Validate

CDISC-TEST	Therapeutic area: Endocrinology	Phase III	Client: CDISC	+ Add Bundle	View	Delete v
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View My Studies – Study Details



CDISCPILLOT01

Study Details

Study Start Date
2012-10-06

Therapeutic Area
Alzheimer's Disease

Phase
II

Client
CDISC

Study Title
Safety and Efficacy of Zanomaline in Patients with Mild to Moderate Alzheimers Disease.

Data Bundles

Data Bundle Issues	SDTM		Data Bundle Clean Data	SDTM	
Last validation date: 2022-04-22T19:32:09			Last validation date: 2022-04-14T15:17:56		
Validate			Validate		

View My Studies – View Details



Dashboard / View My Studies / View details

CDISCPILLOT01 / Issues

Bundle Details Datasets Reports

Standard and Version

SDTM IG v.3.4

Define-XML Version

2.1

Regulatory

CDISC CT

SDTM CT 2020-03-27

WHODrug Version

MedDRA Version

Comment

Datasets with issues to provide reasonable output



Datasets

28



Subjects



Records



Sites



View My Studies – View Details

Dashboard / View My Studies / View details

CDISCPILLOT01 / Issues

Bundle Details **Datasets** Reports

Datasets

Dataset ↑	Label	# Records	Size	Modified Date
AE			21.4 kB	2022-03-17T17:26:44
CM			19.2 kB	2022-03-10T16:26:45
DD	Death Details		4.0 kB	2020-08-21T09:14:25
DI	Device Identifiers		16.4 kB	2020-08-21T09:14:24
DM			9.1 kB	2022-03-23T17:45:02
DS			10.2 kB	2022-03-15T14:51:46



View My Studies – View Details

Dashboard / View My Studies / View details

CDISCPILOT01 / Issues

Bundle Details Datasets **Reports**

Report

Search

<input type="checkbox"/>	Validation Date ↓	# Rejects	# Errors	# Warnings	# Notices	
<input type="checkbox"/>	2022-04-24T14:58:51	0	62	9	0	

Conformance Validator



Choose Datasets

CDISCPILOT01 SDTM

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

Datasets

<input checked="" type="checkbox"/>	Dataset ↑	Label	# Records	Size
<input checked="" type="checkbox"/>	AE			21.4 kB
<input checked="" type="checkbox"/>	CM			19.2 kB
<input checked="" type="checkbox"/>	DD	Death Details		4.0 kB
<input checked="" type="checkbox"/>	DI	Device Identifiers		16.4 kB

Conformance Validator



Dashboard / Conformance Validator / Configure Conformance Rules

Configure Conformance Rules

Data Model: SDTM | Model IG Version: 3.4 | Publisher: CDISC | Proprietary Rules

My Rule Set | Save Rule S

Conformance Rules

Rule ID	Rule Type	Description	Version	Rule Severity
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0007	Value Presence	Raise an error when the date portion of --DTC is an incomplete date and the date portion of DM.RFSTDTC is an incomplete date, but --DY is not empty	1.0	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0008	Value Presence	Raise an error when --TPTREF is empty, but --ELTM is not empty	1.0	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0009	Range & Limit	Raise an error when EPOCH is not in TA.EPOCH	1.0	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0026	Range & Limit	Trigger error when --TPTREF = null and --RFTDTC is populated	1.0	Error
<input checked="" type="checkbox"/> CDISC.SDTMIG.CG0027	Range & Limit	Trigger error when --SCAT is not null and --SCAT is equal to --CAT	1.0	Warning

Versions: CDISC CT SDTM CT 2020-03-27 | UNII | MED-RT

Dictionaries: MedDRA | WHODD | SNOMED



Validation

A validation progress dialog box with a white background and a light gray border. At the top right is a close button (X). In the center is a circular progress indicator showing 99% completion. At the bottom are two buttons: 'Close' and 'Open Report'.

99%

Close Open Report



Issue Reporting

CDISCPILLOT01 / Issues / 2022-04-24T14:58:51 ↓

Issue Summary Issue Details Rules Reports

Search

Dataset ↑	Rule ID	Error Message	Severity	# Issues	Explanation
AE	CDISC.SDTMIG.CG0041	At least one of the Seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE) = 'Y', but AESER = 'N' or empty.	Error	1	
AE	CDISC.SDTMIG.CG0042	If AESER = "N" then none of the seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE) could be equal to "Y".	Warning	3	
AE	CDISC.SDTMIG.CG0050	AEDECOD should be populated when AEPTCD is populated	Error	1	
AE	CDISC.SDTMIG.CG0389	AESCONG is completed, but not equal to "N" or "Y"	Error	1	This issue needs to be resolved



Issue Reporting

Dashboard / View My Studies / View details / Report details

CDISCPIL01 / Issues / 2022-04-24T14:58:51

Issue Summary **Issue Details** Rules Reports

Search

Severity Dataset

Rule ID ↑	Error Message	Severity	Dataset	USUBJID	Record	Sequence	Variable(s)	Value(s)
CDISC.SDTMIG.CG0008	FTPTREF is empty and FTELTM is not empty	Error	FT	CDISC003	958	278	FTELTM, FTPTREF	PT30M,
CDISC.SDTMIG.CG0008	FTPTREF is empty and FTELTM is not empty	Error	FT	CDISC003	959	279	FTELTM, FTPTREF	PT30M,
CDISC.SDTMIG.CG0008	FTPTREF is empty and FTELTM is not empty	Error	FT	CDISC003	960	280	FTELTM, FTPTREF	PT30M,
CDISC.SDTMIG.CG0009	EPOCH is not in TA.EPOCH	Error	DS	CDISC002	6	3	EPOCH	TREATMENT1



Issue Reporting

Dashboard / View My Studies / View details / Report details

CDISCPIL01 / Issues / 2022-04-24T14:58:51

Issue Summary Issue Details **Rules Reports**

Search

Rule ID ↑	Message
CDISC.SDTMIG.CG0007	The date portion of --DTC is not complete date or the date portion of DM.RFSTDTC is not complete date, but --DY is not empty
CDISC.SDTMIG.CG0008	--TPTREF is empty and --ELTM is not empty
CDISC.SDTMIG.CG0009	EPOCH is not in TA.EPOCH
CDISC.SDTMIG.CG0026	--RFTDTC is populated when --TPTREF is null

Status

Status

Success

Success

Success

Skipped



View My Studies – View Details

Dashboard / View My Studies / View details

CDISCPILLOT01 / Issues

Bundle Details Datasets Reports

Report

Search

<input type="checkbox"/>	Validation Date ↓	# Rejects	# Errors	# Warnings	# Notices	
<input type="checkbox"/>	2022-04-24T14:58:51	0	62	9	0	



Issue Reporting

A		B
1	Conformance Details	
2	Study	CDISCPILOT01
3	Bundle	Issues
4	Report Generation	2022-04-24T14:58:51
5	Total Runtime	166 seconds
6	Transaction ID	71f9b9fa-df84-4f71-b519-a1cd477b81db
7		
8		
9		
10		
11	Study Details	
12	Therapeutic Area	Alzheimer's Disease
13	Phase	II
14	Client	CDISC
15	Study Start Date	2012-10-06
16		
17		
18		
19		
20		
21	Bundle Details	
22	Standard	SDTM
23	Version	V3.4
24	CT Version	2020-03-27
25	Define-XML Version	2.1
26	UNII Version	Not configured
27	Med-RT Version	Not configured
28	MedDRA Version	Not configured
29	WHODRUG Version	Not configured
30	SNOMED Version	Not configured
31		
32		
33		
34		
35		

Navigation: Conformance Details | Issue Summary | Issue Details | Rules Report | +



CORE on GitHub

- 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

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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 transitioned to a GitHub-based 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

A screenshot of the GitHub repository page for 'cdisc-org / cdisc-rules-engine'. The page shows the repository name, navigation tabs for Code, Issues (61), Pull requests (2), Discussions, Actions, Projects (1), Wiki, Security, and Insights. Below the navigation, there are statistics for the repository: 'main' branch, 60 branches, and 49 tags. A 'Go to file' button and a 'Code' button are visible. The commit history shows a recent commit by 'nhaydel' titled 'Update version.py' with 459 commits, and two folders: '.github' (fix paths for cli executables, 5 months ago) and 'cdisc_rules_engine' (Rule schema updates (#246), last month).

A screenshot of the README.md file content. It shows the title 'cdisc-rules-engine' and the subtitle 'Open source offering of the cdisc rules engine'. The text is displayed in a clean, white background with a light gray border.

Thank you!

Questions?

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