



CORE: New Open Source Validation Tool from CDISC

July 2024



Michelle Lumicao
Principal Data
Standards Specialist

Michelle Lumicao is a Principal Data Standards Specialist at Syneos Health, where she is a member of the Data Standards and Governance group as an SDTM SME. She has more than 17 years of experience in clinical research. She worked in Data Management for 4 years and in Statistical Programming 13 years. She has been a CDISC volunteer for CORE and the Digital Health Technologies Team.

Disclaimer and Disclosures

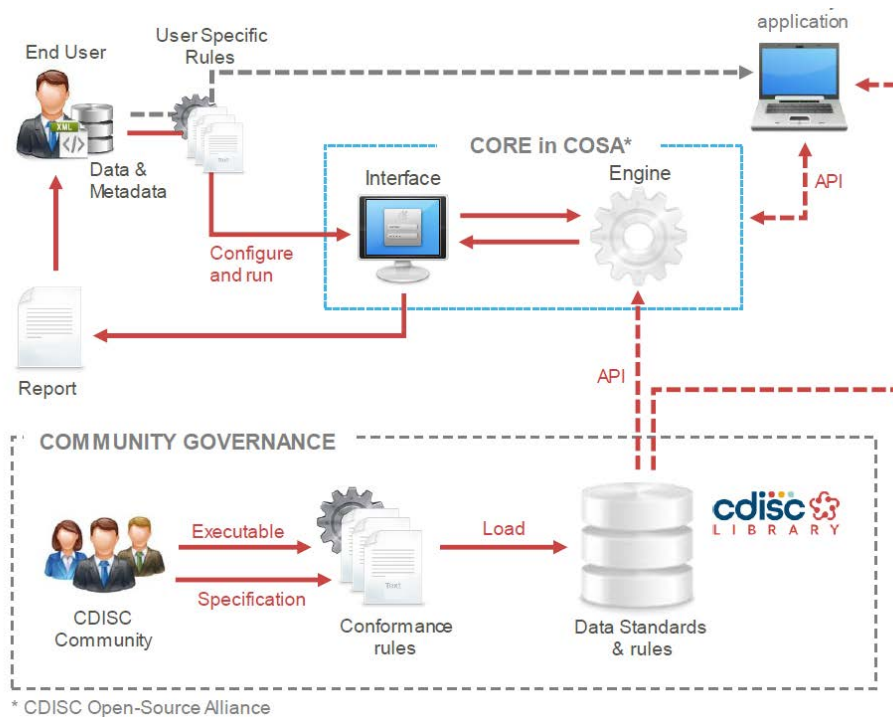
The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of Syneos Health.

CDISC Open Rules Engine (CORE)

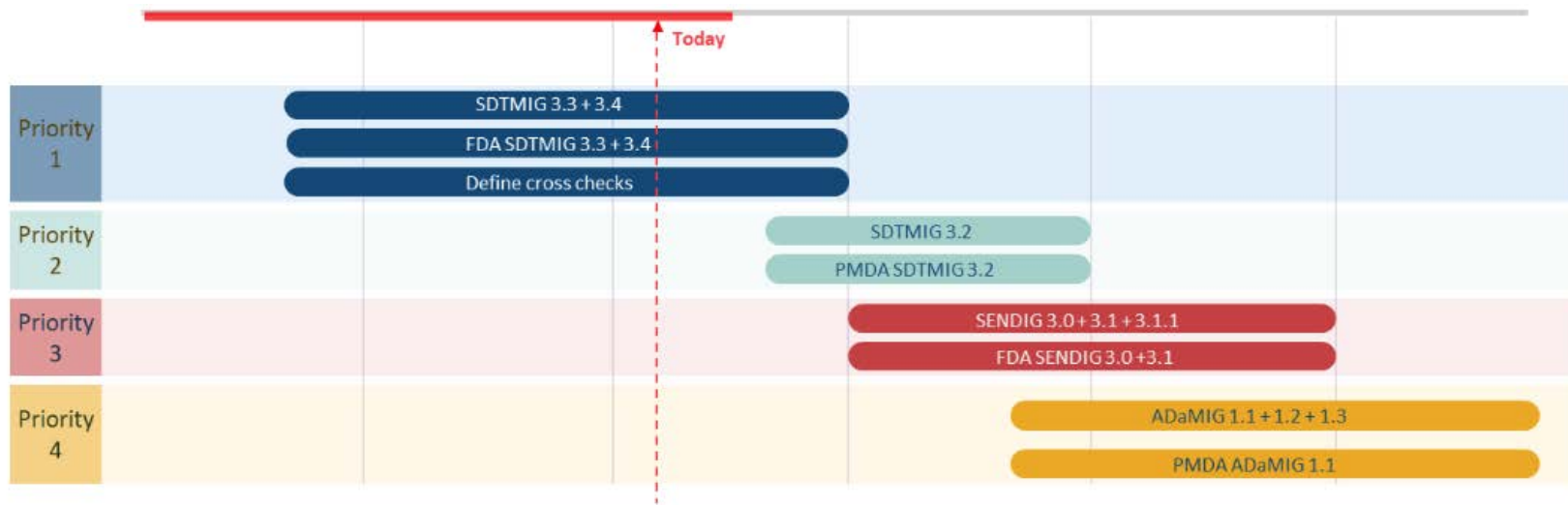
- CDISC creates Conformance Rules in descriptive text file format that serve as guidance for the correct implementation of the CDISC standards in a clinical study.
- Currently, FDA uses Pinnacle 21 to check if data is compliant with the Conformance Rules.
- The main goals of CORE are to:
 - Have one version of truth of Conformance Rules
 - Create unambiguous and executable Conformance Rules for CDISC standards
 - Provide a Reference Implementation of an open-source execution engine for the executable Rules.
- <https://www.cdisc.org/core>



CORE Project Concept



CORE Project Timeline (from CDISC website – July 2024)



➡ *Timelines depend on community engagement*

Previous CORE Program Roadmap (October 2022)



Volunteers for CORE Minimum Viable Product

- Accenture
- Atlantic Research Group
- Boehringer Ingelheim
- Business & Decision Life Sciences
- C&R Research
- ClinChoice
- d-Wise
- Dizal Pharma
- EPAM
- Gilead
- GlaxoSmithKline
- Harbour Biomed
- ICON
- Johnson & Johnson
- Merck
- Microsoft
- Novartis
- Parexel
- PHASTER
- Pinnacle 21
- Pfizer
- PPD
- PRA Health Sciences
- Roche
- Sanofi
- SGS Health Science
- Southern Star Research
- Syneos Health
- Vita Data Sciences
- Wemedoo

Volunteering in CORE

Used YAML to create executable conformance rules

Core ID	Rule Type	Creator	
CDISC.SDTMIG.CG0110	Value Presence	Malini Narreddy	
CDISC.SDTMIG.CG0108	Value Presence	Malini Narreddy	
CDISC.SDTMIG.CG0107	Variable Presence	Malini Narreddy	
CDISC.SDTMIG.CG0106	Value Presence	Malini Narreddy	
CDISC.SDTMIG.CG0105	Variable Presence	Malini Narreddy	
CDISC.SDTMIG.CG0104	Range & Limit	Elisa Young	
CDISC.SDTMIG.CG0103	Variable Presence	Elisa Young	
CDISC.SDTMIG.CG0102	Range & Limit	Michelle Lumicao	
CDISC.SDTMIG.CG0101	Range & Limit	Michelle Lumicao	
CDISC.SDTMIG.CG0100_duplicate_do_not_use	Value Presence	Steve Fitzpatrick	
CDISC.SDTMIG.CG0100	Range & Limit	Els Janssens	
CDISC.SDTMIG.CG0099	Value Presence	Elisa Young	
CDISC.SDTMIG.CG0098	Variable Presence	Elisa Young	

All 593 rules loaded.

EDIT

TEST

```
1 Authority:
2   Organization: CDISC
3 Check:
4   all:
5     - name: EXTRT
6       operator: equal_to
7       value: PLACEBO
8     - name: EXDOSE
9       operator: not_equal_to
10      value: 0
11 Citations:
12   - Cited Guidance: Doses of placebo should be represented by EXTRT = "PLACEBO" and
13     EXDOSE = "0" (indicating 0 mg of active ingredient was taken or administered).
14   Document: SDTMIG v3.4
15   Item: Assumption 2b
16   Section: 6.1.3.1
17 Core:
18   Id: CDISC.SDTMIG.CG0102
19   Version: '1'
20 Description: When EXTRT is PLACEBO, EXDOSE must equal 0
21 Outcome:
22   Message: EXTRT is PLACEBO, but EXDOSE is not equal to 0.
23 Output Variables:
24   - EXTRT
25   - EXDOSE
26 References:
27   - Origin: SDTM and SDTMIG Conformance Rules
28   Rule Identifier:
29     Id: CG0102
30     Version: '1'
31     Version: '2.0'
32 Rule Type: Range & Limit
33 Scopes:
34   Classes:
35     Include:
36       - Interventions
37   Domains:
38     Include:
39       - EX
40   Standards:
41     - Name: SDTMIG
42     Version: '3.4'
43 Sensitivity: Record
44 Severity: Error
45
```

How to Access CORE (GitHub)

<https://www.cdisc.org/core>

Home / CORE

CORE



Overview

Program Highlights

Participate

Presentations

FAQ

CORE on GitHub

Latest page content update: 17 Jan 2024

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 the open-source 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 Engine Reference Implementation in GitHub

- 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)
 - The GitHub-based Engine is provided with a command line interface (CLI) and not with a Graphic User Interface (UI).
 - Provision with a CLI provides implementers with the maximum flexibility while integrating the CORE Engine into their processing environments.
- Accessed at the GitHub CDISC-rules-engine repository, including special instructions in the Readme file

Non-CDISC Vendor Implementation

- Formedix CORE
 - Formedix built a downloadable application that bundled the CORE engine
- Pinnacle 21 Community
 - [P21 Adds Support for CDISC Open Rules Engine \(CORE\) | Pinnacle 21](#)
- XML4Pharma
 - Smart Submission Dataset Viewer implemented CORE

When will FDA use CORE?

- Still early in the process, but CDISC believes that one version of the truth will benefit the regulatory submission ecosystem
- In January 2024, CDISC announced a collaboration with the FDA to incorporate FDA Business Rules into CORE
 - Started in November 2023 and has a term of 3 years
 - Goal is to collaborate on providing input on machine-executable formats of the FDA Business Rules and on the development and ongoing governance of this set of executable rules within CORE that can be used by sponsors of medical product applications.



“Our research collaboration with CDISC is an important step to ensure that study data validation rules are understandable and accessible to all.”

■ Lilliam Rosario, Ph.D., Director, Office of Computational Science, Office of Translational Sciences, CDER

Michelle Lumicao
Principal Data Standards Specialist
Michelle.Lumicao@syneoshealth.com

Shortening the Distance from Lab to Life[®].

