Syneos Health

CORE: New Open Source Validation Tool from CDISC

July 2024

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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.

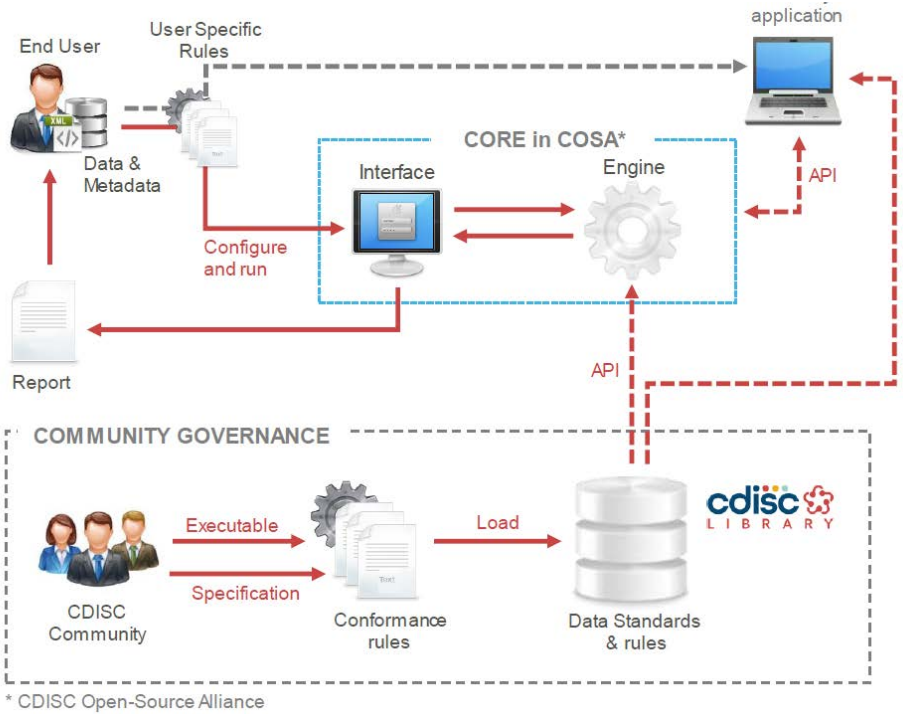
Disclaimer and Disclosures

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.

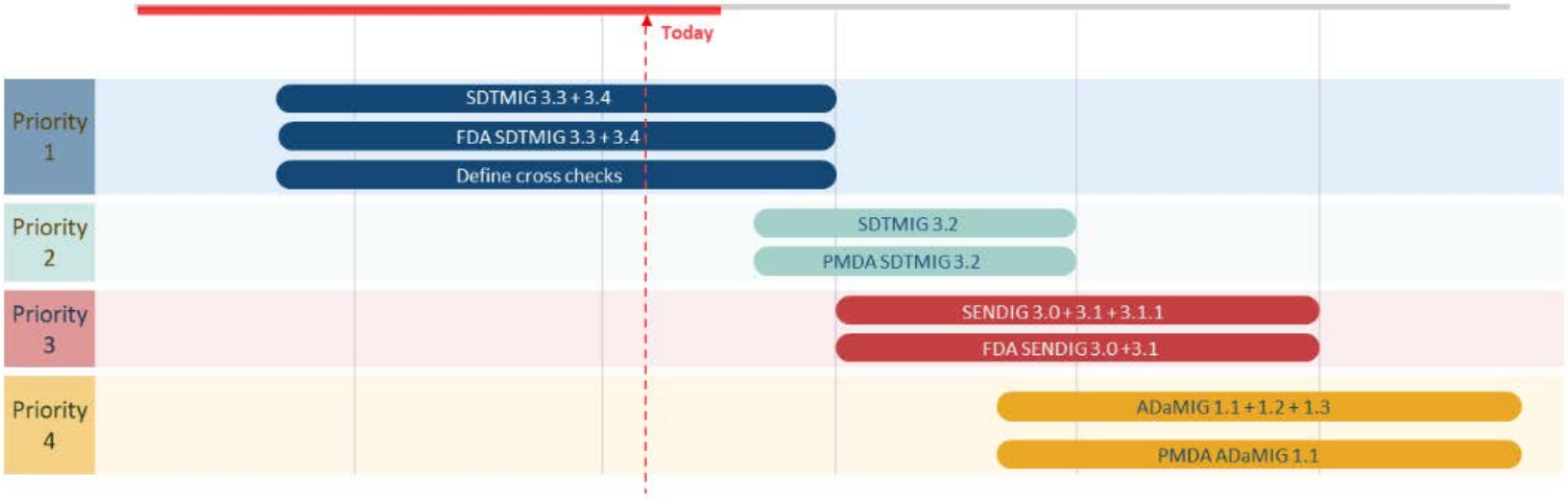
CDISC Open Rules Engine (CORE)

- 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

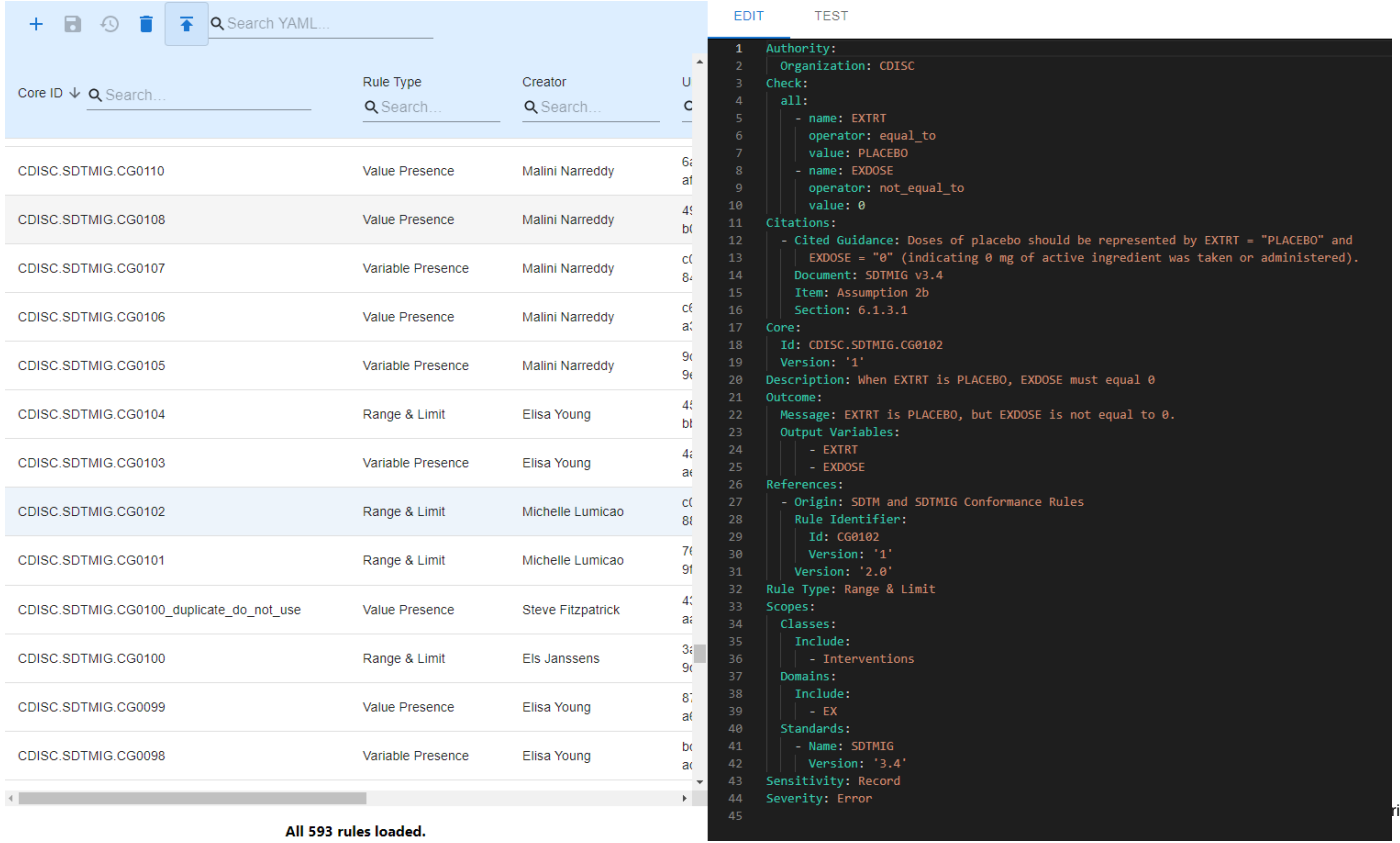
Previous CORE Program Roadmap (October 2022)

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

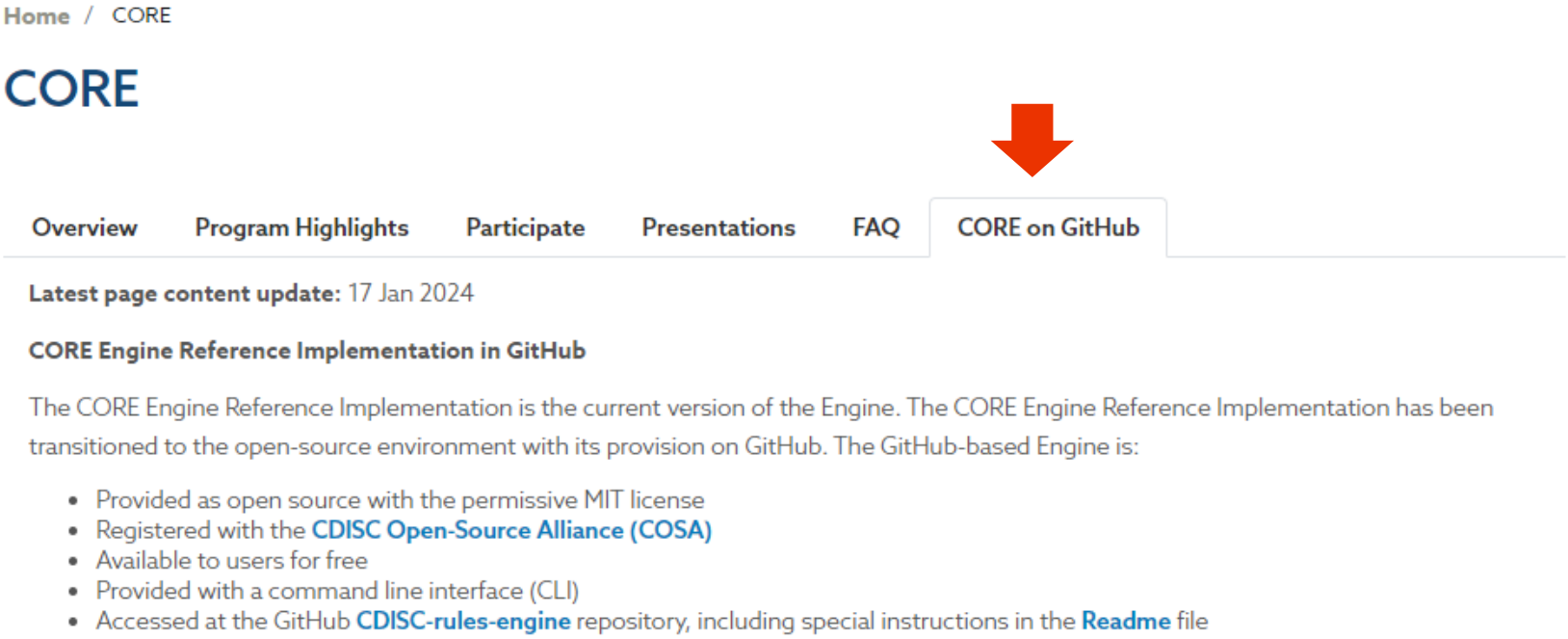
Volunteering in CORE

Used YAML to create executable conformance rules



How to Access CORE (GitHub)

https://www.cdisc.org/core



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

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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.

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“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

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