WITH STANDARDS – UNLOCK THE POWER OF DATA

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2022
JAPAN
INTERCHANGE
13-14 JUNE | VIRTUAL EVENT

CORE: The CDISC Open Rules Engine

Presented by Peter Van Reusel, Chief Standards Officer, CDISC

Meet the Speaker

Peter Van Reusel

Title: Chief Standards Officer
Organization: CDISC

Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

He previously served as CDISC's European Liaison, shepherding relationships with key European regulatory, academic, and biopharma stakeholders. Peter is also an active PHUSE collaborator.

Agenda

1. CORE Concept
2. CORE Overview
3. CORE MVP Evaluation Release
4. CORE Roadmap Board
5. CORE Next Steps
6. CORE Participation

CORE Concept

Why is CDISC doing CORE?

- Ensure each standard has a set of unambiguous, executable Conformance Rules
- Ensure consistency across Conformance Rule implementations
- Expedite the availability of executable Conformance Rules for new Foundational Standards
- Create executable Conformance Rules vetted by the CDISC standards development teams
- Develop an open-source engine that serves as a Reference Implementation
- Publish the Rules in the CDISC Library and the engine under the CDISC Open Source Alliance (COSA)

https://www.cdisc.org/core

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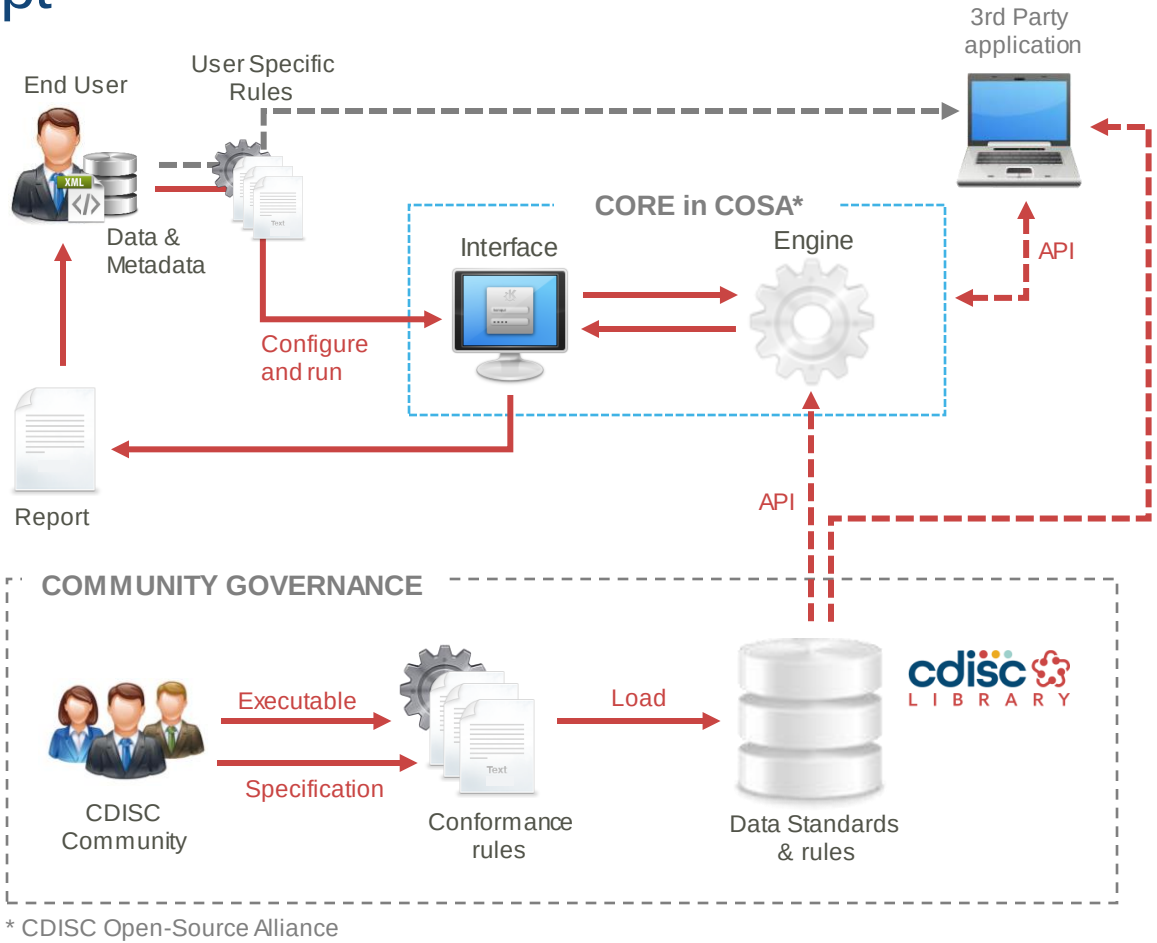
CORE Concept



* CDISC Open-Source Alliance

CORE Overview

CORE Program Roadmap

Q3 2023 – Q2 2024

Production Release 2: Rich, easy to use and intuitive platform

- **Engine:** Open-Source under COSA; evolved; maintained by CDISC
- **Conformance Rules:** New CDISC Standards released with Conformance Rules
- **Functionality:** Advanced functionality
- **Deployments:** Vendor- or user-provided cloud & local production environments

Q3 2022 – Q2 2023

Production Release 1: Full conformance checking platform

- **Engine:** Open-Source under COSA; evolved; maintained by CDISC
- **Conformance Rules:** Remainder of CDISC Foundational Standards
- **Functionality:** Complete conformance checking functionality
- **Deployments:** Vendor- or user-provided cloud & local production environments

Establish CORE Roadmap Board

Q3 2021- Q2 2022

Evaluation Release 0: Minimum Viable Product

- **Engine:** Open-Source, developed by CDISC, published under COSA
- **Conformance Rules:** SDTM 2.0 and SDTMIG 3.4
- **Functionality:** Basic conformance checking functionality
- **Deployments:**
  - CDISC-provided public cloud evaluation environment
  - Private cloud evaluation environment
  - Stand-alone evaluation deployment

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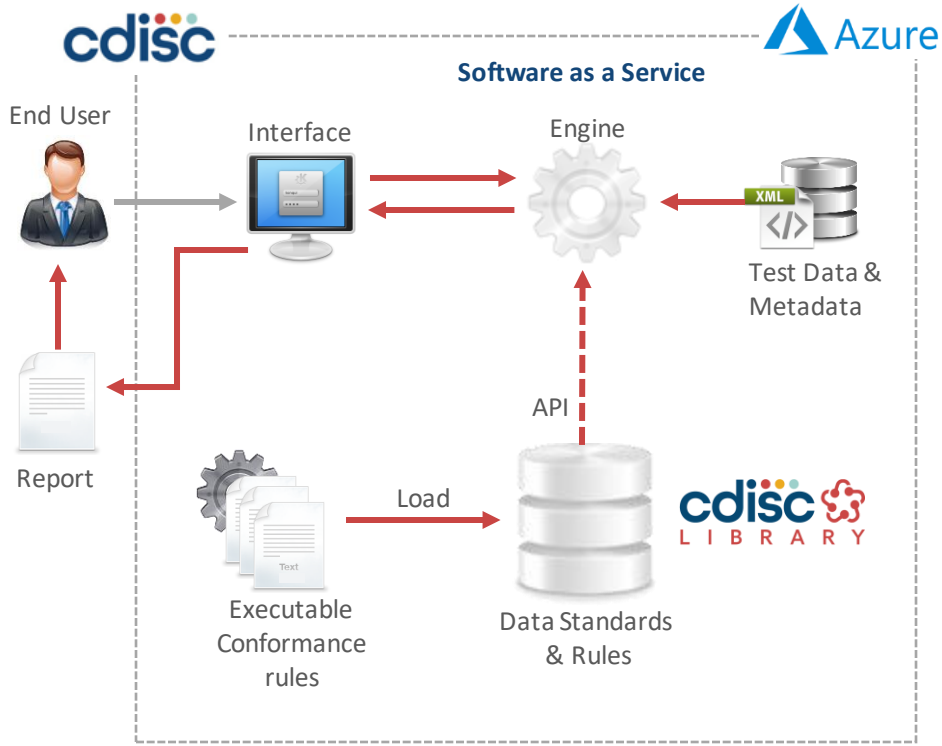
Vendor/User

CDISC-Provided Cloud Evaluation Deployment

Deployment Attributes

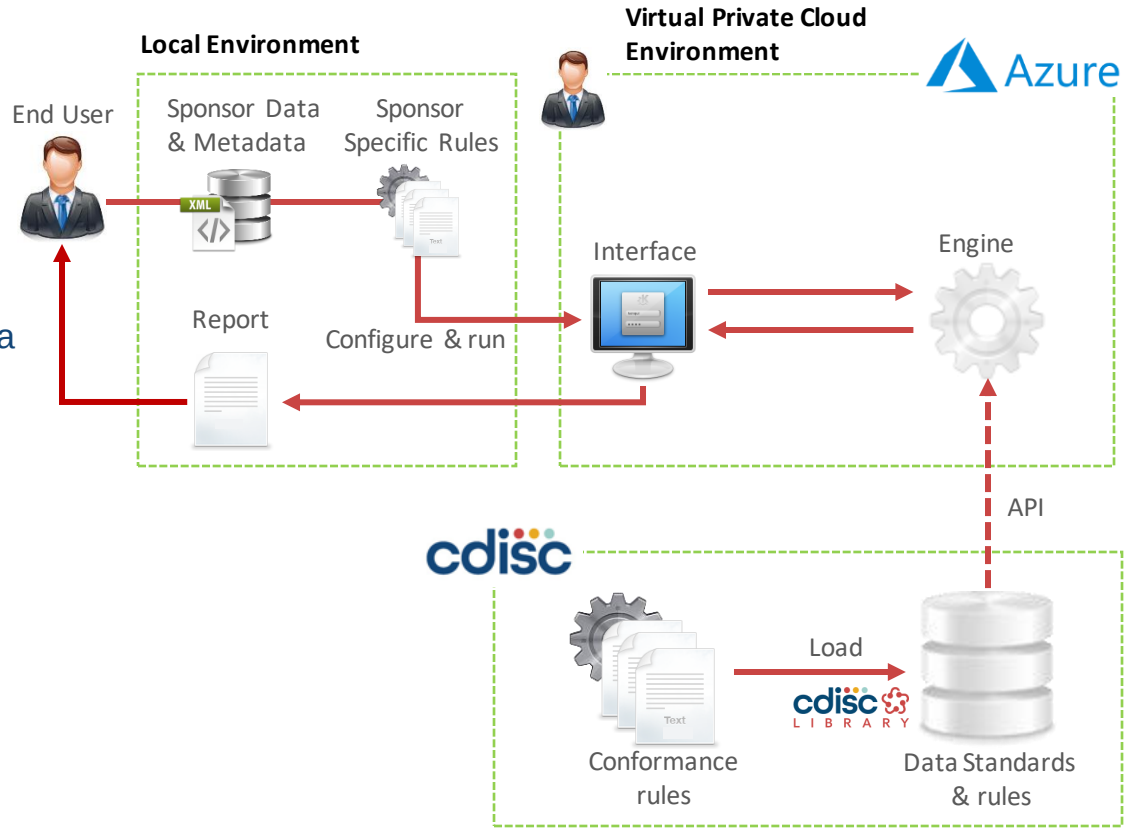
- CDISC-provided SaaS public cloud environment
  - Quick account creation
- A development version for user evaluation
- Test data and rules provided by CDISC and not extendible
- Simple environment for hands-on introduction
- See key CORE features in action, on limited data and metadata
- Users cannot execute with their own data and rules



Planned Virtual Private Cloud Evaluation Deployment

Deployment Attributes

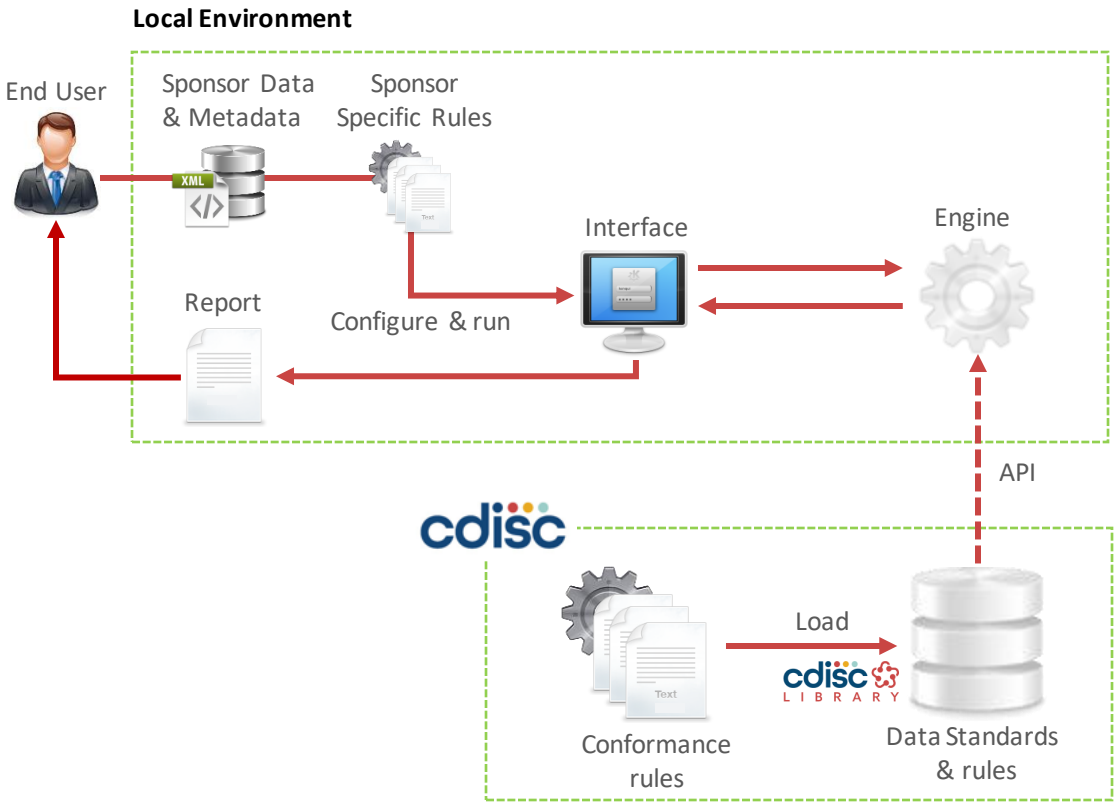
- Private cloud environment
  - Some setup required
- A development version for user evaluation, released via Azure Marketplace
- Engine executes in cloud, but user data reside locally
- A simple environment for hands-on introduction, including ability to add sponsor-defined rules
- Evaluate CORE features on different studies



Planned On-premises Evaluation Deployment

Deployment Attributes

- On-premises environment
- Engine executes locally, and user data reside locally
- A simple environment for hands-on introduction, including ability to add sponsor-defined rules
- Evaluate CORE features on user's study data

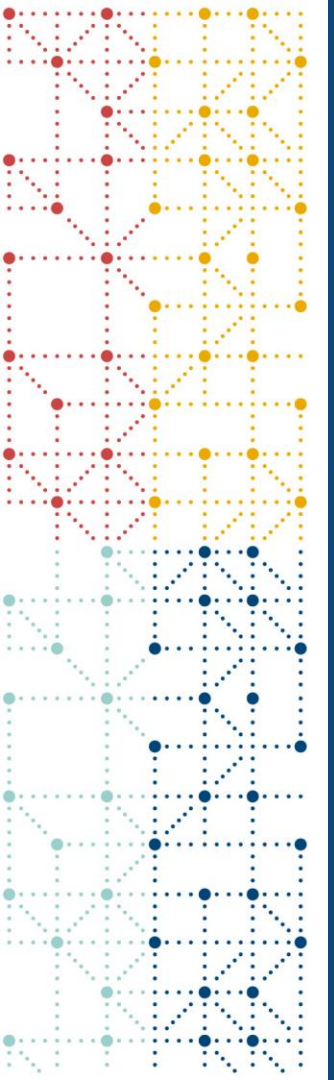


CORE Facts and Considerations

- The CDISC CORE project includes development of
  - (1) executable Conformance Rules for the CDISC standards
  - (2) a Reference Implementation of a software engine (CORE) to execute these rules
- CDISC will publish the executable Conformance Rules in the CDISC Library
- CDISC will provide free access to the CDISC Library and Conformance Rules
- CORE will be published as open-source (MIT license)
- CDISC has no plans to deploy CORE as commercial software
- CORE has a basic UI to control rules execution
- CDISC plans for the CORE UI to allow 'plug-in' functionality

CORE Facts and Considerations

- Implementers may choose to develop a different engine or adapt CORE
  - The Reference Implementation can confirm that a proprietary engine achieves the correct results
- The initial release of CORE will run on Azure cloud
- Developers will have the option to prepare CORE for
  - On-premises deployment
  - An alternative cloud platform deployment
  - Running from command line, integrating with other systems



CORE MVP Evaluation Release

Rules Content Development

- Primary focus for CORE MVP Evaluation Release is machine-executable rules published for SDTMIG v3.4
- Reviewed over 450 rules for inclusion in CORE
  - 350 machine-executable
  - Completed 200+ rules for MVP phase 1 (CDISC-provided cloud deployment)
  - Remaining rules for MVP phase 2 (planned private cloud and stand-alone deployments)
- Also planned- small set of SENDIG, ADaMIG, and Regulatory rules for MVP phase 2
- 11-step development process in use, from draft through publication
  - Centered around the web-based Rule Editor
  - Rule authors draft rules in the Rule Editor
  - Rule authors create test data to perform both positive and negative tests for each rule
  - Separate QC is performed prior to publication in CDISC Library and CORE

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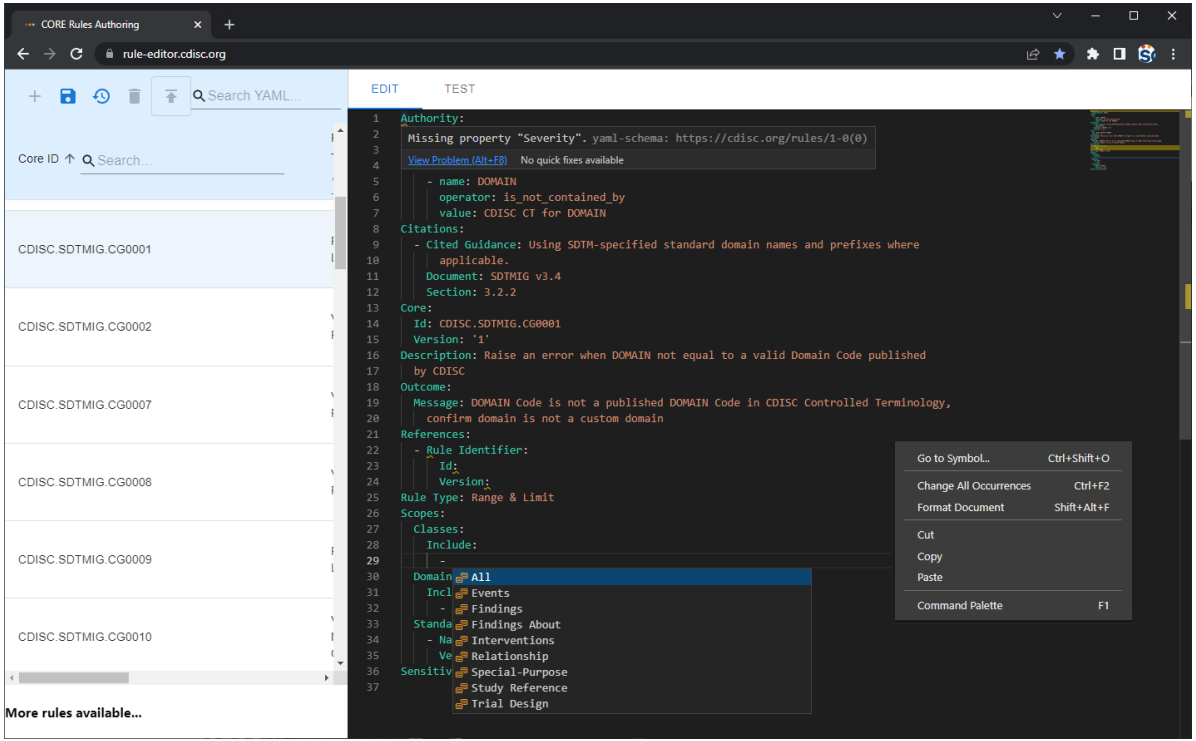
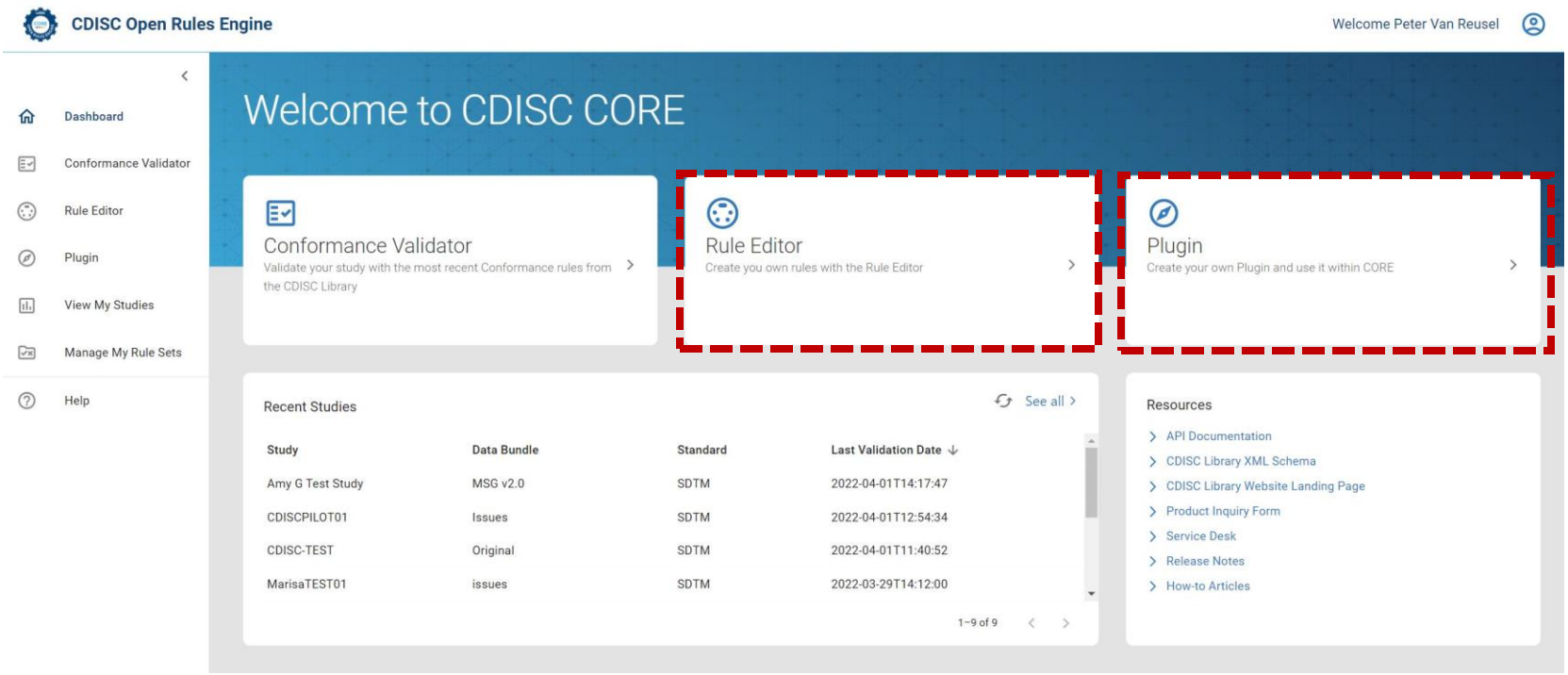
Rule Editor

- Web-based editor
  - YAML specification
  - Conversion to JSON machine-executable code+
  - Connection to Rule Engine via CORE API
- Supports unit testing
- Integrated into CORE UI



CORE UI Dashboard



Testing and Validation

- Two overall CORE validation objectives
  - Ensure Rules and engine are fully tested
  - Prepare full Rules and engine validation package for industry
    - Industry will then validate installation and operation of the Rules and engine
- Parallel testing activity by software and Rules dev teams
  - Software dev team:
    - Unit test each requirement
    - Test the CORE API
    - UAT of the UI
    - Test Rules and engine with broader test study data
  - Rules dev team:
    - Prepare test data to trigger “positive” and “negative” condition per Rule
    - Execute these tests with the CORE engine
    - Supported by the Rule Editor tool
- CORE Validation Plan will be completed and executed before the production CORE Reference Implementation is released

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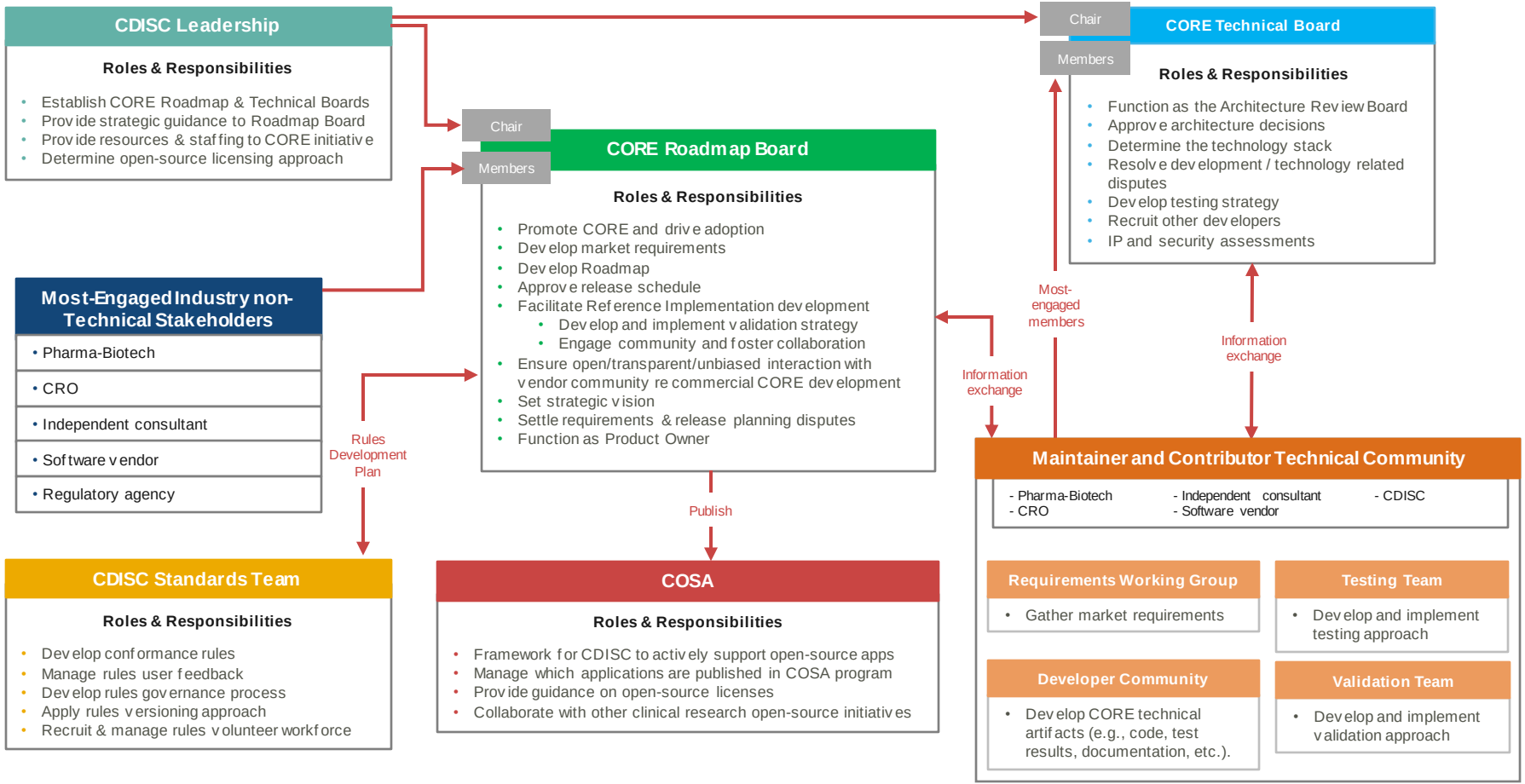
CORE Roadmap Board

Roadmap Board

- CDISC is committed to ensure that the CORE conformance rules standard and rules engine are widely adopted in the industry

- A rich ecosystem comprised of CDISC, CORE users, and CORE software vendors is needed to ensure that:
  - Industry collaborates on development and maintenance of the conformance rules
  - The standard conformance rules are actively governed by the CDISC community
  - Market requirements for enhanced CORE system solutions are identified and shared with industry stakeholders

CORE Development: Landscape of Responsibilities & Participation



CORE Next Steps

CORE Rules Delivery Planning

Phase 1

CORE Engine

- SDTMIG v3.4 Conformance Rules
- Sample SEND, ADaM, and Regulatory Rules
- Machine Executable

Phase 2

- SDTMIG v3.2 and v3.3 Conformance Rules
- SENDIG Rules
- ADaMIG Rules
- Regulatory Authority Rules

Phase 3

- Evaluate and Develop New Content
- Refinement of Existing Rules

Complete Q2 2022

Complete Q1 2023
SDTMIG v3.2 and v3.3 Rules

Complete Q2 2023
SENDIG Rules

Complete Q3 2023
ADaMIG Rules

Begin Q1 2023

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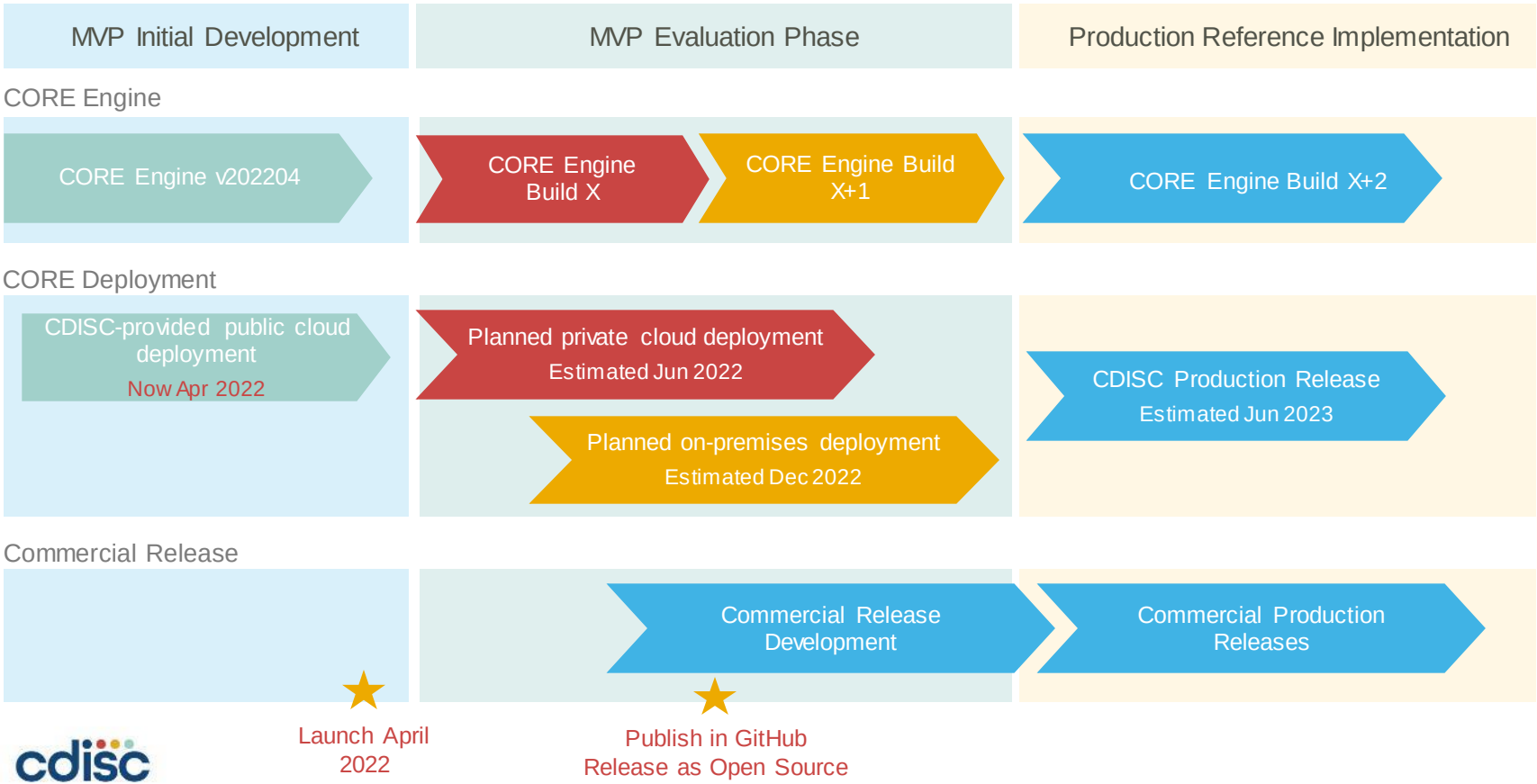
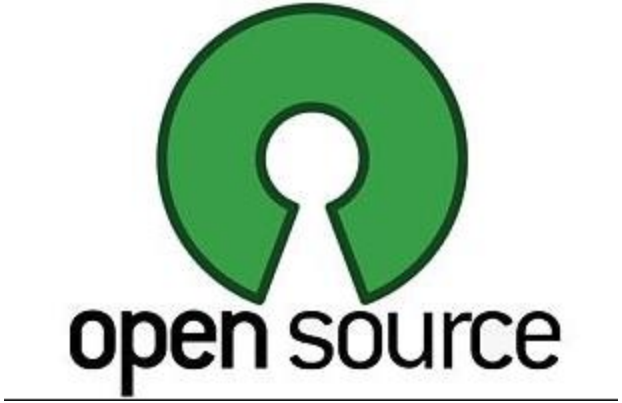
CORE Engine Planning



CORE license

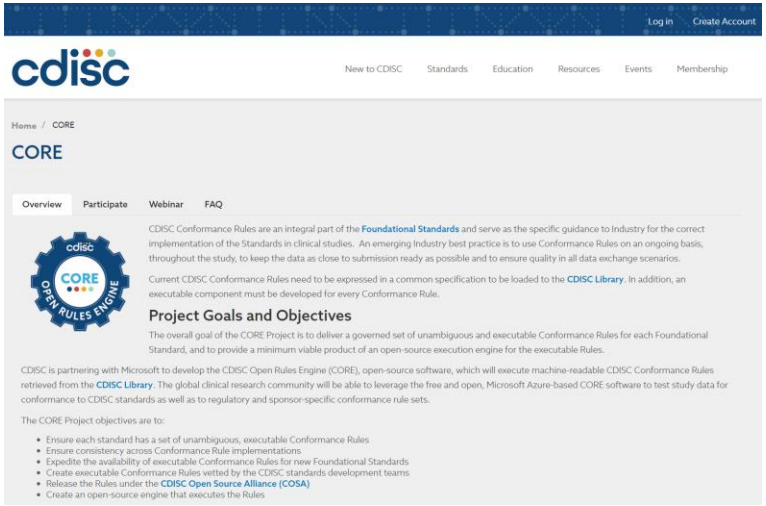


- MIT license
  - Permissive
  - Simple
  - Widely used
  - Low-risk
  - Works for commercial or non-commercial usage
- Contributors License Agreement (CLA)
  - Will not use a CLA
  - Rely on the GitHub inbound = outbound clause in Terms of Service
- Optimize project for ease of participation and deployment
  - The open-source development model helps ensure sustainability

CORE will be released as open-source

- Currently planning to release CORE as open-source after the next MVP release
- Tasks prior to releasing as open-source:
  - Code refactoring
  - Technical documentation
  - Move to GitHub
  - CORE community
- MIT license
  - Permissive
  - Simple
  - Widely used
  - Low-risk
  - Works for commercial or non-commercial usage

Get Involved!



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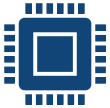
Commercial vendor involvement



A variety of commercial alternatives

Examples:

Software-as-a-Service

Commercial support

Embedded in commercial software

Deployment and implementation services

Vendors contribute to the open-source community

Examples:

Contributors

Maintainers

Board members

API and Plugin architecture promote tool development

Examples:

Issue Management

Define-XML Authoring

Workflow

CORE Deployment Alternatives

Examples:

Alternative User Interface

On-premises version

Multi-cloud version

Embedded deployment

Alternative rule engine

CORE Participation

Now and in Future

Participation

- Over 80 individuals from 50+ organizations around the world have participated on the CORE Dev Team
- Many are new to CDISC, and this is their first time serving as a CDISC volunteer. The team is a very active, global group.
- Continued volunteer participation and community support remain critical
- The following graphic identifies the 50+ organizations participating

accenture
Clupea
GenInvo™
novo nordisk
SDC
Statistics & Data Corporation
abbvie
C&R Research
HARBOUR BIOMED
PAREXEL
SGS Health Science
AMGEN
Dizal Pharma
迪哲医药
ICON
PHASTER
上海君實生物醫藥科技股份有限公司
Shanghai Junshi Biosciences Co., Ltd.
ARG
Atlantic Research Group
dMed
绵脉
Inductive Quotient
.Research .Bigdata .Analytics
PINNACLE 21
SHIONOGI
Boehringer Ingelheim
d-wise™
IMPACT THERAPEUTICS
Pfizer
Southern Star RESEARCH
Business & Decision
Life Sciences
迪时
Data Science Express
IQVIA
POINT CROSS
Syneos Health
BioForum
The Data Masters
epam
Johnson & Johnson
PPD
Taimei
太美医疗科技
CERTARA
EPHICACY
MERCK
VITA DATA SCIENCES
a division of SOFTWORLD
ClinChoice
GILEAD
Microsoft
Roche
VELS
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gsk GlaxoSmithKline
NOVARTIS
SANOFI
Wemedoo
Clinical Information Specialists

CORE Resources Now and in the Future

*The Rules Development Team has over 65 members, **BUT** only a small team of volunteers and CDISC staff authored rules*

- Training materials in development
- Quarterly training sessions to onboard new rule authors
- "Call for Volunteers" webinar June 7th
- Planning rules development workshops
  - CDISC US Interchange
  - PHUSE EU Connect

Wanted: ADaM, SDTM, and SEND Volunteers!

Thank You!

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