

WITH STANDARDS – UNLOCK THE POWER OF DATA



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

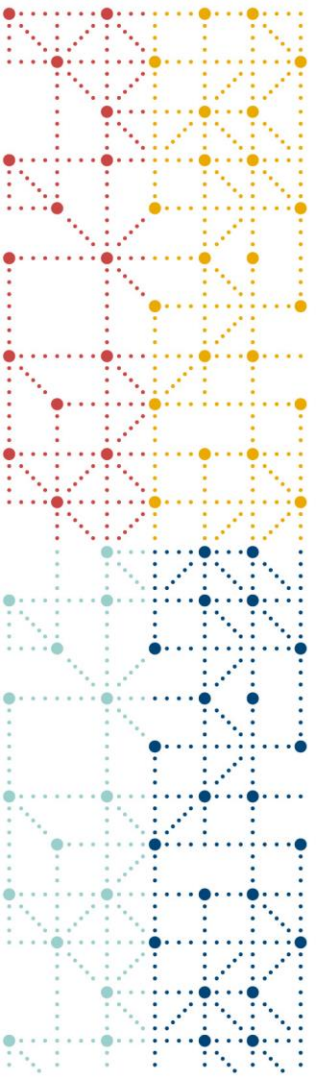
Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma 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

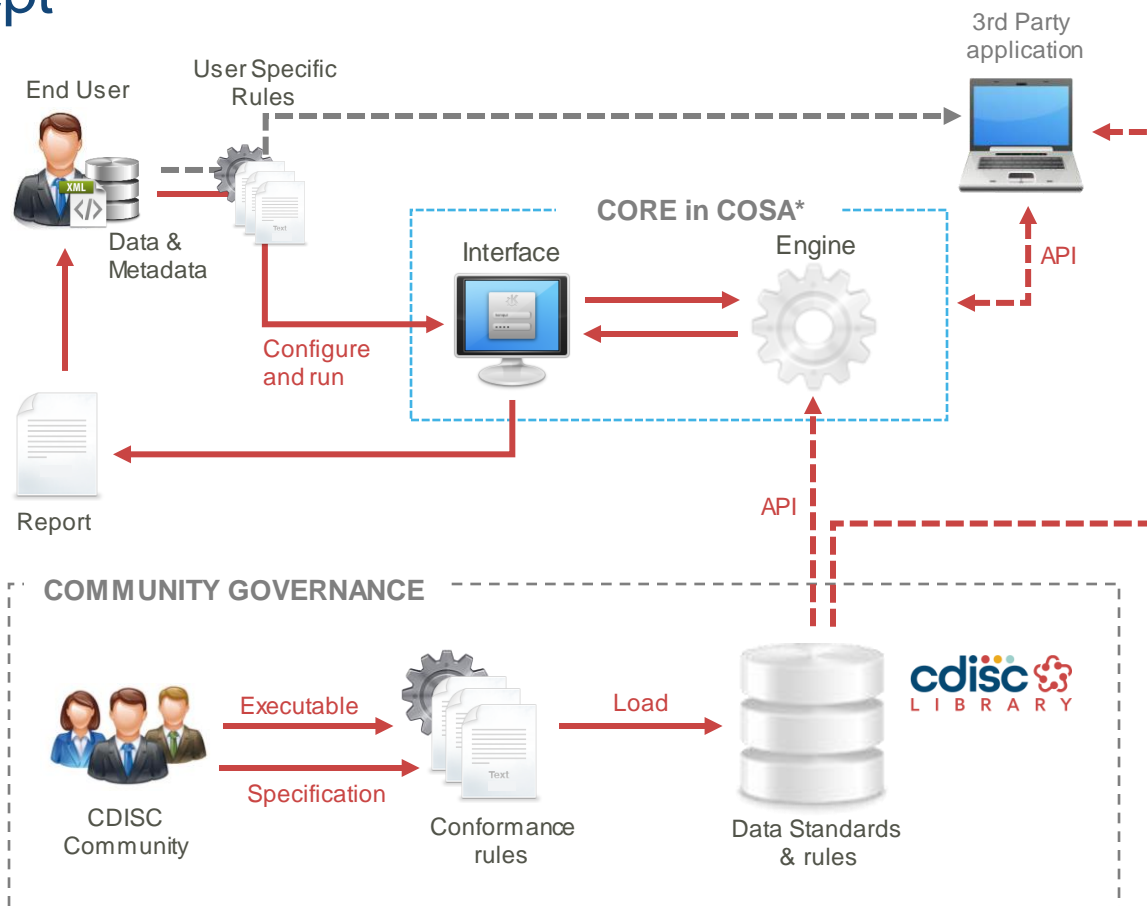
Why is CDISC doing CORE?

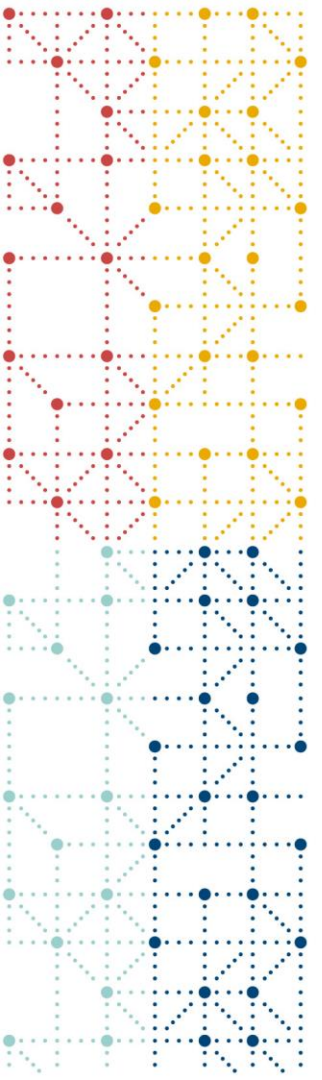
- Ensure each standard has a set of unambiguous, executable Conformance Rules
- Ensure consistency across Conformance Rule implementations
- Expedite the availability of executable Conformance Rules for new Foundational Standards
- Create executable Conformance Rules vetted by the CDISC standards development 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>

CORE Concept





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

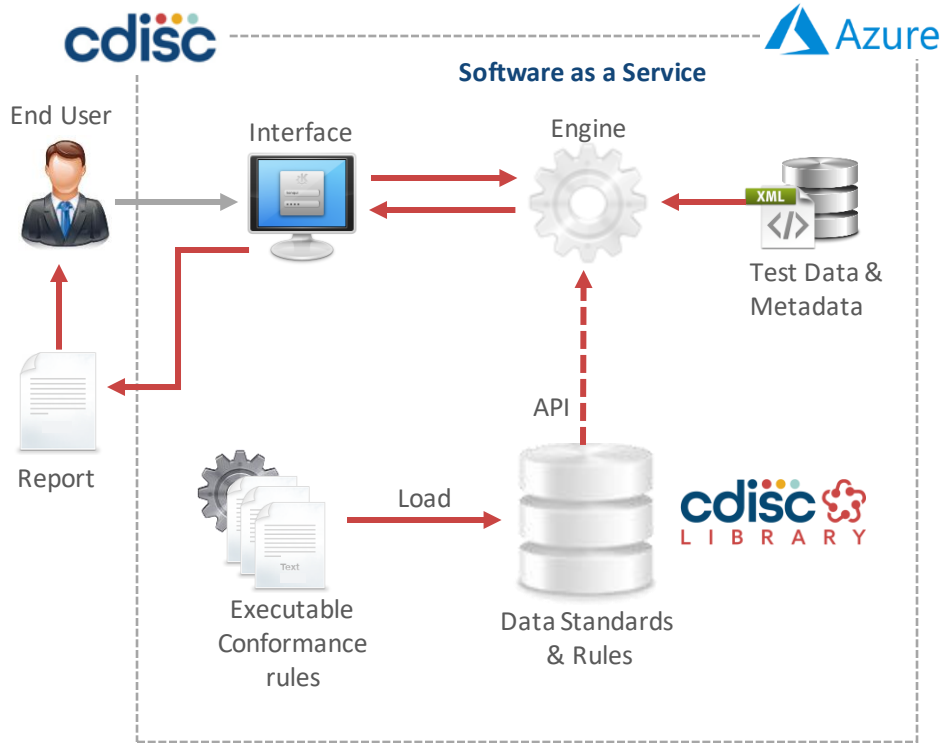
Evaluation Release 0: Minimum Viable Product

- **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

CDISC-Provided Cloud Evaluation Deployment

Deployment Attributes

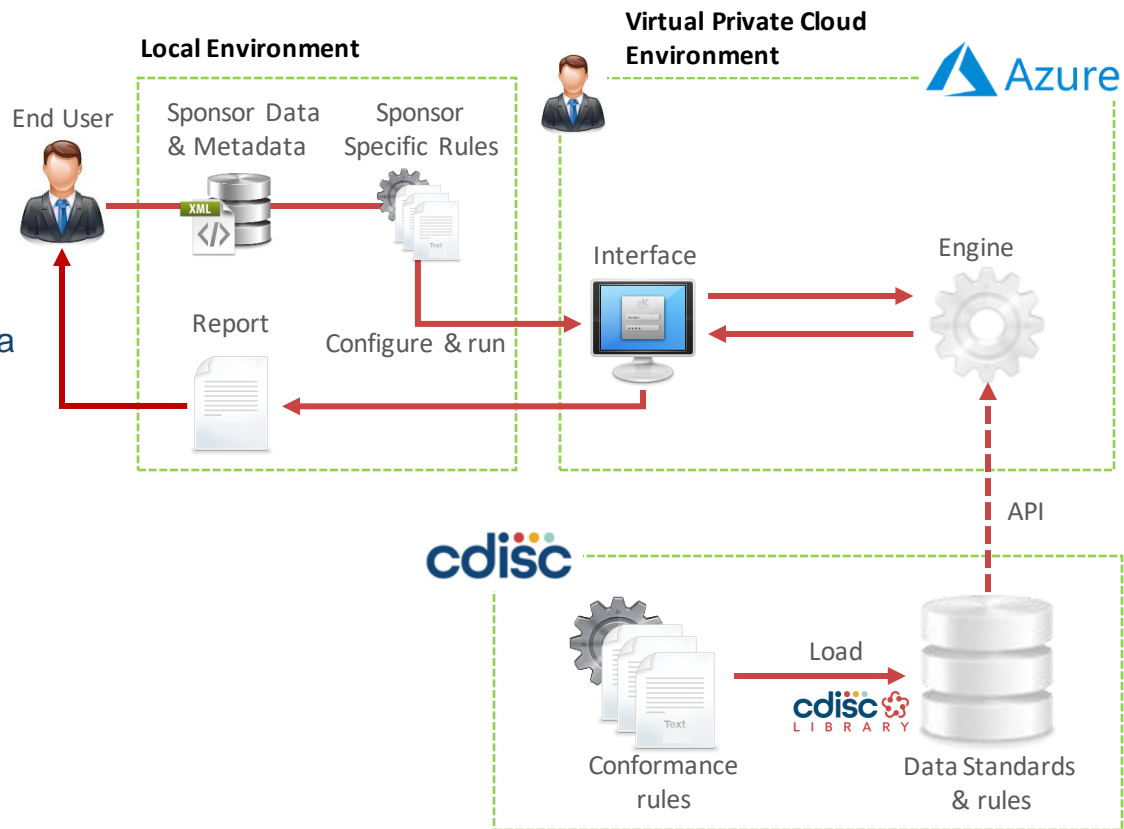
- CDISC-provided SaaS public cloud environment
 - Quick account creation
- A development version for user evaluation
- Test data and rules provided by CDISC and not extendible
- Simple environment for hands-on introduction
- See key CORE features in action, on limited data and metadata
- Users cannot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



Planned Virtual Private Cloud Evaluation Deployment

Deployment Attributes

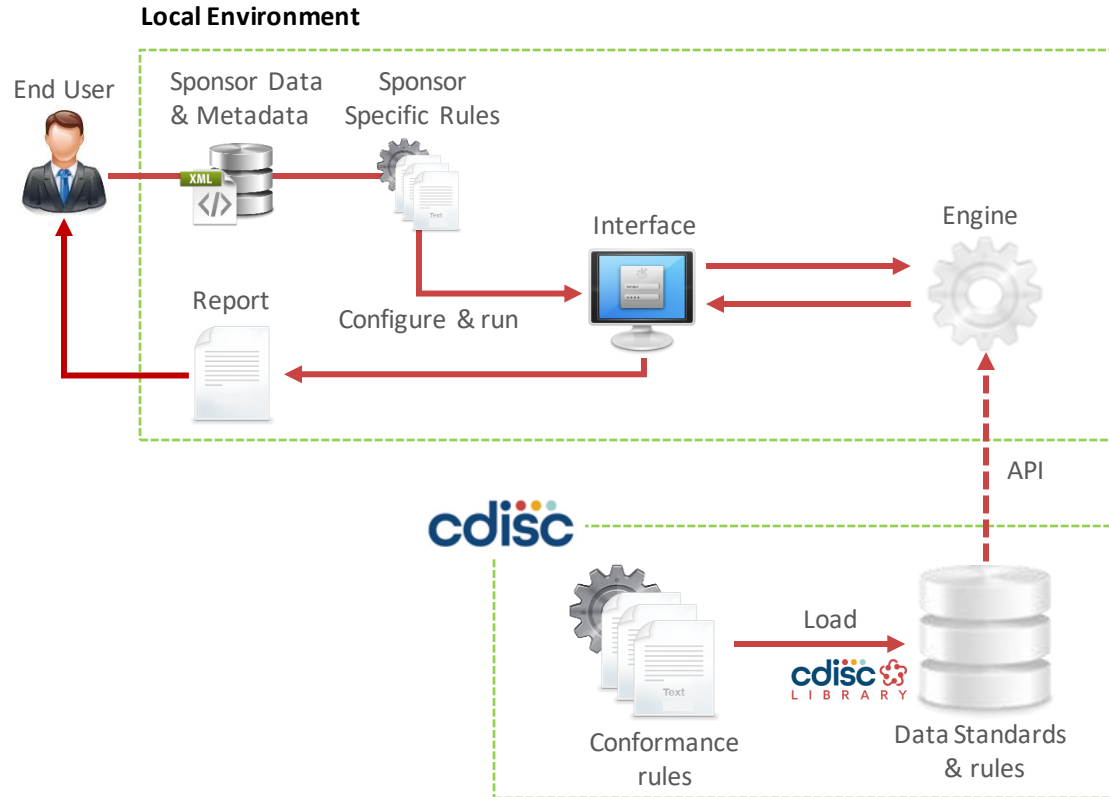
- Private cloud environment
 - Some setup required
- A development version for user evaluation, released via Azure Marketplace
- Engine executes in cloud, but user data reside locally
- A simple environment for hands-on introduction, including ability to add sponsor-defined rules
- Evaluate CORE features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

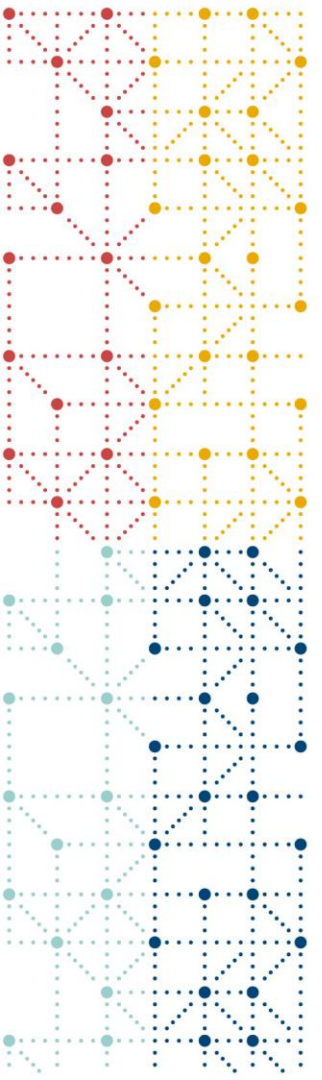


CORE Facts and Considerations

- 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

The screenshot shows the 'CORE Rules Authoring' web application in a browser. The address bar displays 'rule-editor.cdisc.org'. The interface is split into two main panels: a left sidebar and a main editor area.

Left Sidebar: A list of rules with 'Core ID' and a search bar. The visible rules are:

- CDISC.SDTMIG.CG0001
- CDISC.SDTMIG.CG0002
- CDISC.SDTMIG.CG0007
- CDISC.SDTMIG.CG0008
- CDISC.SDTMIG.CG0009
- CDISC.SDTMIG.CG0010

At the bottom of the sidebar, it says 'More rules available...'

Main Editor Area: Titled 'EDIT TEST', it shows a YAML rule configuration for a 'Domain' rule. The configuration includes:

- Authority:** Missing property "Severity".
- Citations:** Cited Guidance: Using SDTM-specified standard domain names and prefixes where applicable. Document: SDTMIG v3.4, Section: 3.2.2
- Core:** Id: CDISC.SDTMIG.CG0001, Version: '1'
- Description:** Raise an error when DOMAIN not equal to a valid Domain Code published by CDISC
- Outcome:** Message: DOMAIN Code is not a published DOMAIN Code in CDISC Controlled Terminology, confirm domain is not a custom domain
- References:** Rule Identifier: Id, Version; Rule Type: Range & Limit
- Scopes:** Classes: Include: - Domain

A context menu is open over the 'Domain' class, listing various domain types: All, Events, Findings, Findings About, Interventions, Relationship, Special-Purpose, Study Reference, and Trial Design.

At the bottom right, a 'Command Palette' is visible with the following items:

- Go to Symbol... (Ctrl+Shift+O)
- Change All Occurrences (Ctrl+F2)
- Format Document (Shift+Alt+F)
- Cut
- Copy
- Paste
- Command Palette (F1)

CORE UI Dashboard



CDISC Open Rules Engine

Welcome Peter Van Reusel



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

See all >

Study	Data Bundle	Standard	Last Validation Date ↓
Amy G Test Study	MSG v2.0	SDTM	2022-04-01T14:17:47
CDISCPIL01	Issues	SDTM	2022-04-01T12:54:34
CDISC-TEST	Original	SDTM	2022-04-01T11:40:52
MarisaTEST01	issues	SDTM	2022-03-29T14:12:00

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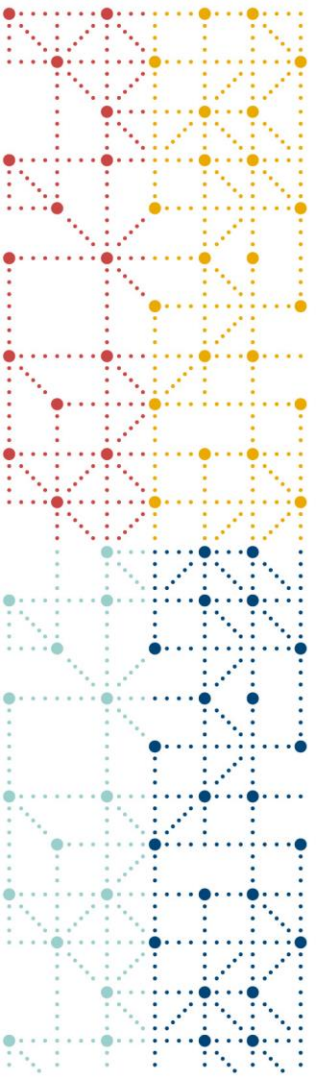
Resources

- > API Documentation
- > CDISC Library XML Schema
- > CDISC Library Website Landing Page
- > Product Inquiry Form
- > Service Desk
- > Release Notes
- > How-to Articles



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



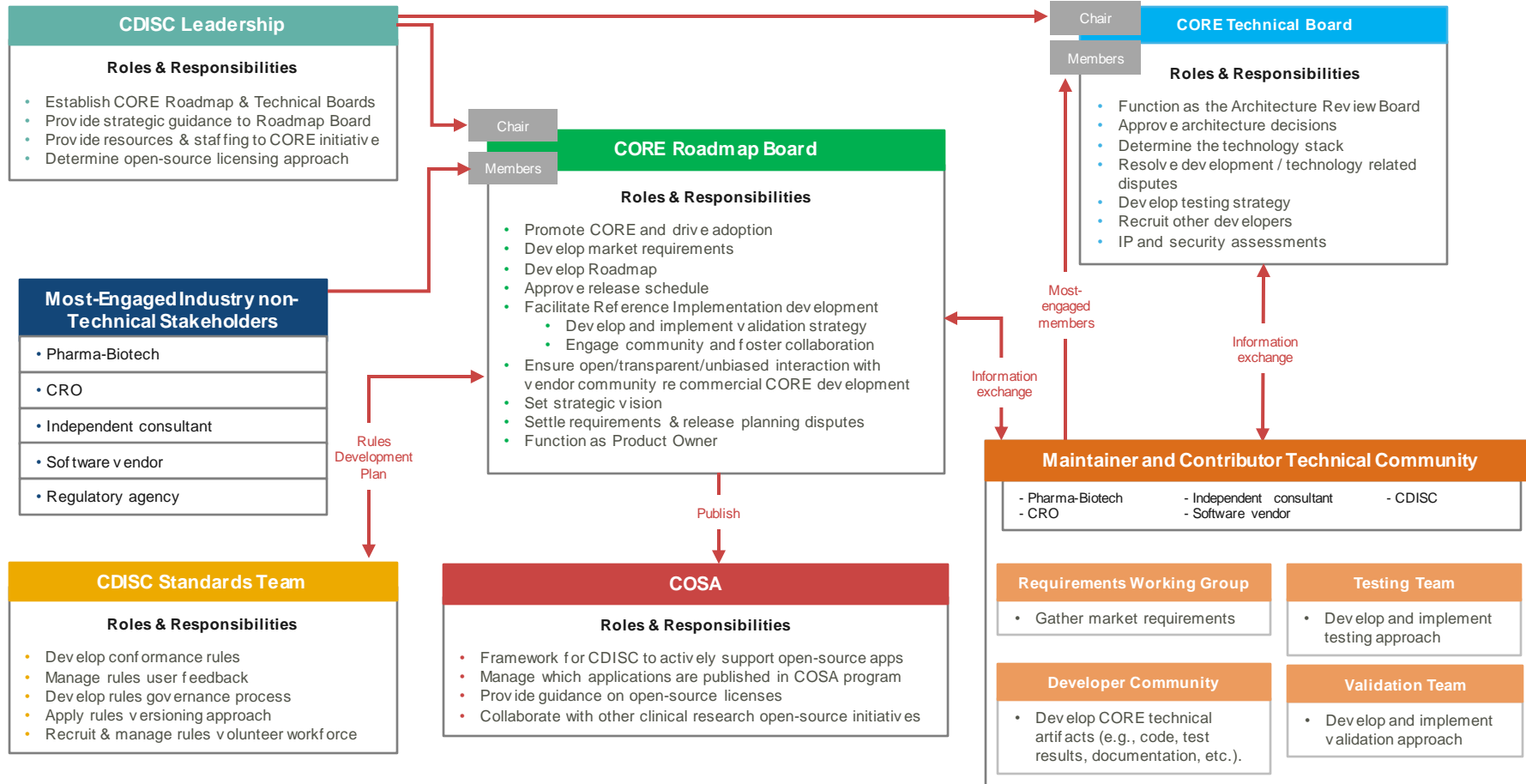
CORE Roadmap Board

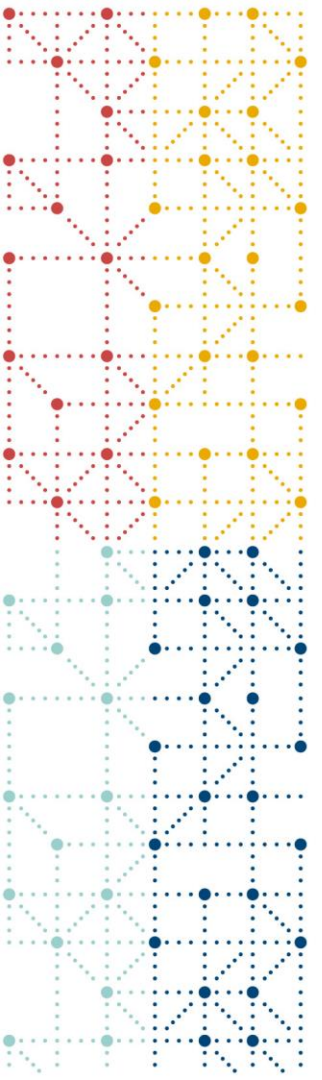


Roadmap Board

- 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

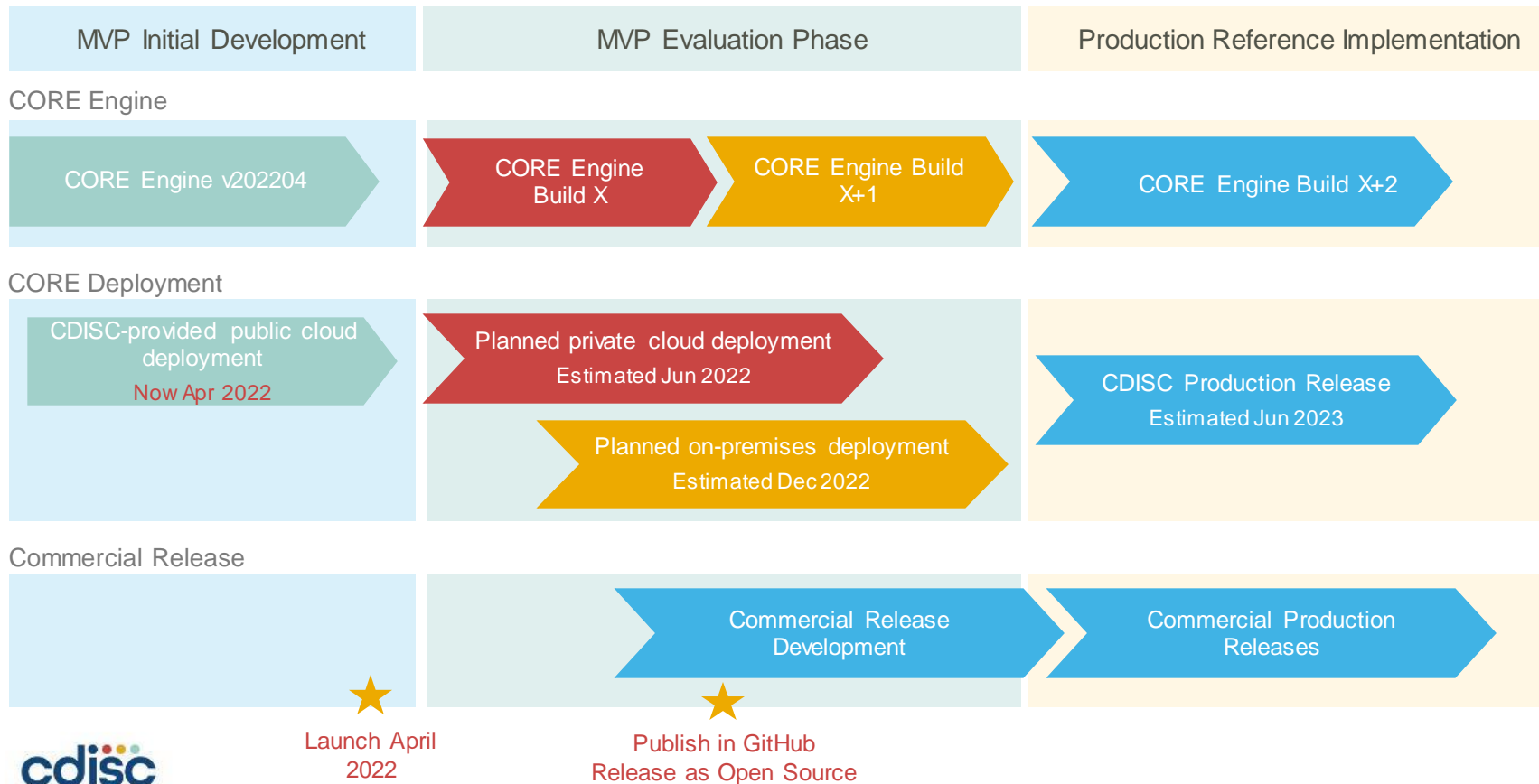
Complete Q1 2023
SDTMIG v3.2 and v3.3 Rules

Begin Q1 2023

Complete Q2 2023
SENDIG Rules

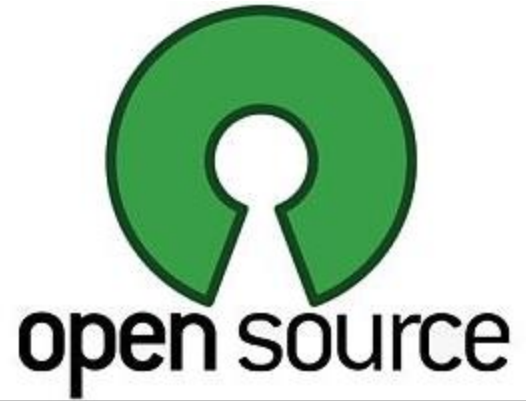
Complete Q3 2023
ADaMIG Rules

CORE Engine Planning



CORE license

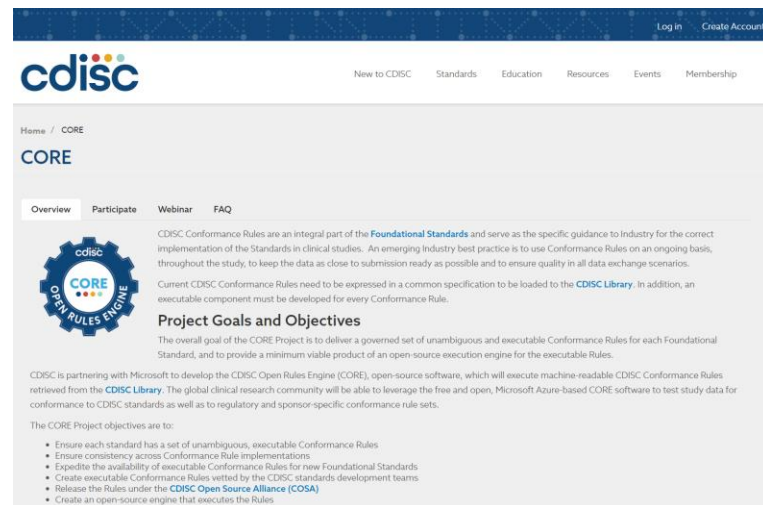
- MIT license
 - Permissive
 - Simple
 - Widely used
 - Low-risk
 - Works for commercial or non-commercial usage
- Contributors License Agreement (CLA)
 - Will not use a CLA
 - Rely on the GitHub inbound = outbound clause in Terms of Service
- Optimize project for ease of participation and deployment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

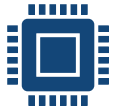


The screenshot shows the CDISC website's page for CORE. At the top, there is a navigation bar with 'Log In' and 'Create Account' links. Below the CDISC logo, there are links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', and 'Membership'. The main content area is titled 'CORE' and includes a breadcrumb 'Home / CORE'. There are tabs for 'Overview', 'Participate', 'Webinar', and 'FAQ'. A circular logo for 'CDISC CORE OPEN RULES ENGINE' is displayed. The text explains that CDISC Conformance Rules are an integral part of the Foundational Standards and serve as specific guidance for clinical studies. It mentions that current rules need to be expressed in a common specification for the CDISC Library. The 'Project Goals and Objectives' section states the goal is to deliver a governed set of unambiguous and executable Conformance Rules for each Foundational Standard. It also notes that CDISC is partnering with Microsoft to develop the CDISC Open Rules Engine (CORE), open-source software that will execute machine-readable CDISC Conformance Rules. The overall goal is to provide a minimum viable product of an open-source execution engine. The CORE Project objectives are listed as:

- 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
- Release the Rules under the CDISC Open Source Alliance (COSA)
- Create an open-source engine that executes the Rules

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

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:

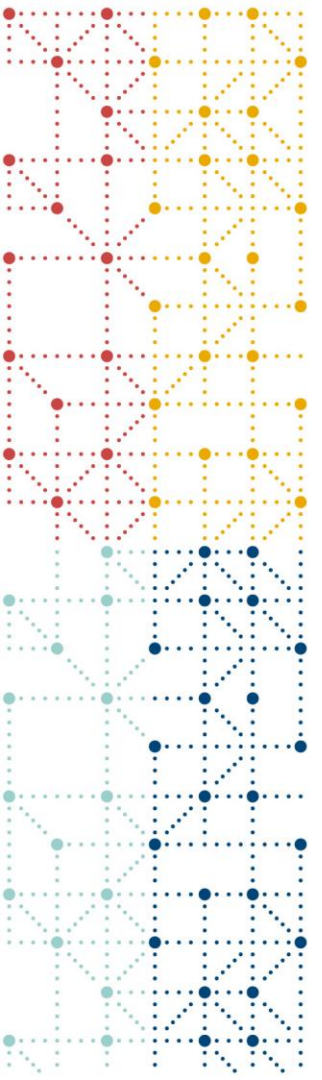
Issue Management
Define-XML Authoring
Workflow



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

abbvie

AMGEN

ARG
ATLANTIC RESEARCH GROUP

Boehringer
Ingelheim

Business & Decision
Life Sciences

Bioforum
THE DATA MASTERS

CERTARA

ClinChoice

cdisc

Clupea

C&R
RESEARCH

Dizal Pharma
迪哲医药

dMed
缔脉

d-wise

迪时
Data Science Express

epam

EPHICACY

GILEAD

gsk
GlaxoSmithKline

GenInvo

HARBOUR
BIOMED

ICON

Inductive Quotient
.Research .Bigdata .Analytics

IMPACT
THERAPEUTICS

IQVIA

Johnson & Johnson

MERCK

Microsoft

NOVARTIS

novo nordisk

PAREXEL

PHASTER

PINNACLE 21

Pfizer

POINT
CROSS

PPD

PRIMHEALTHSCIENCES

Roche

SANOFI

SOC
STATISTICS & DATA CORPORATION

SGS Health Science

上海君實生物醫藥科技股份有限公司
Shanghai Junshi Biosciences Co., Ltd.

SHIONOGI

Southern Star
RESEARCH

Syneos
Health

Taimei
太美医疗科技

VITA DATA SCIENCES
a division of SOFTWAREWORLD

VELS

Wemedoo
Clinical Information Specialists

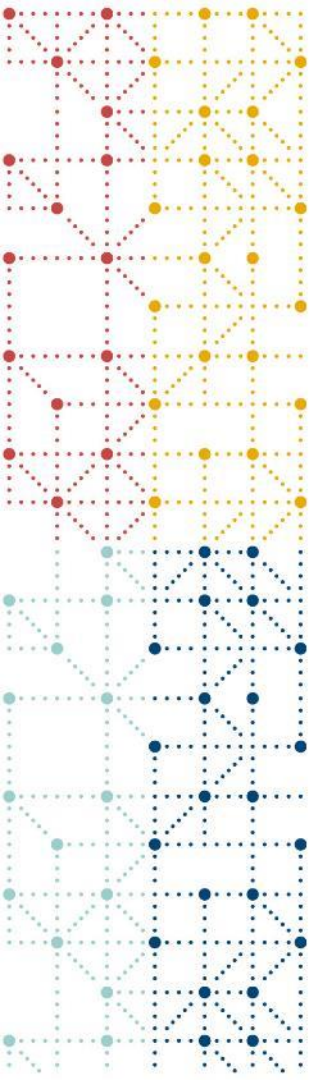
CORE Resources Now and in the Future



*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!

