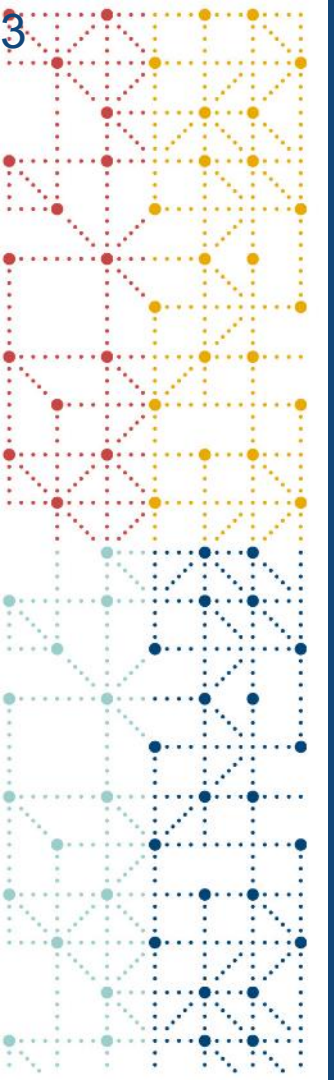
CDISC Open Rules Engine (CORE) Call for Participation Webinar

TUE 20 JUL
11:00AM-12:30PM ET

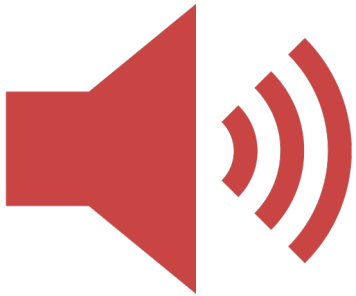
Today's Agenda

1. Housekeeping
2. Feature Presentation + Q&A
3. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping

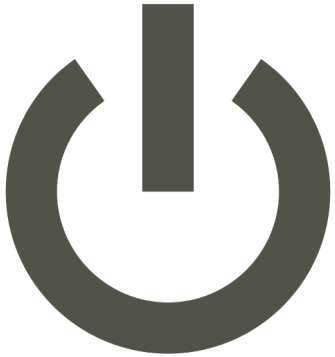


You will remain on **mute**

Housekeeping

Submit questions at any time –
this webinar is an open forum

Housekeeping



Audio issues?

Shut down & restart Zoom app

Housekeeping

A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website

CDISC Open Rules Engine (CORE) Call for Participation Webinar

TUE 20 JUL
11:00AM-12:30PM ET

CDISC Open Rules Engine (CORE)

Call for Participation Webinar

July 20, 2021

Introduction of Presenters

- Dave Evans – CDISC
- Anne-Sophie Bekx – J&J
- Peter Van Reusel - CDISC
- Amy Palmer - CDISC

- Q&A Panel participants
  - Steve Matteson, Venkata Maguluri (Pfizer)
  - Tianna Umann, David Crawford (Microsoft)
  - Brian Jackson, Jon Vandergrift (Accenture)
  - Charles Shadle (CDISC)
  - Nick De Donder (Business & Decision Life Sciences)

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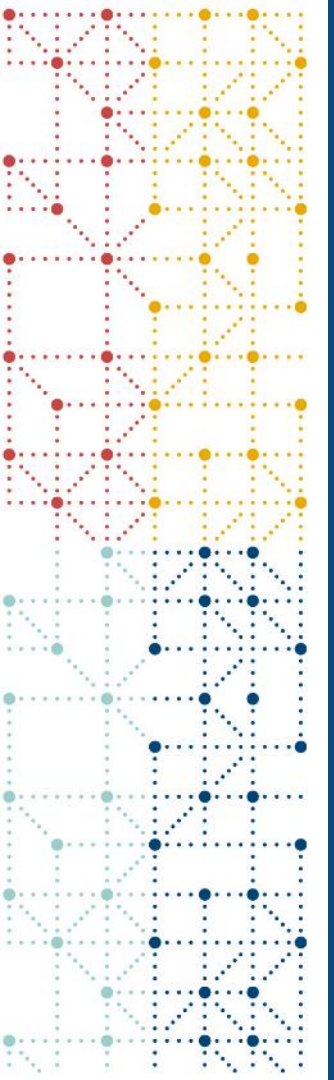
Agenda

1. 1. Why is CDISC doing CORE?
2. 2. CORE Presentation
3. 3. Call for Participation
4. 4. Q&A



Why is CDISC Doing CORE?

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CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

Why is CDISC doing CORE?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

Automation requires:

- *Standard Machine-executable content for Useability*
- *Standard Technology Interfaces for Integration for Accessibility*
- *Standard Verification and Conformance Rules for Integrity*

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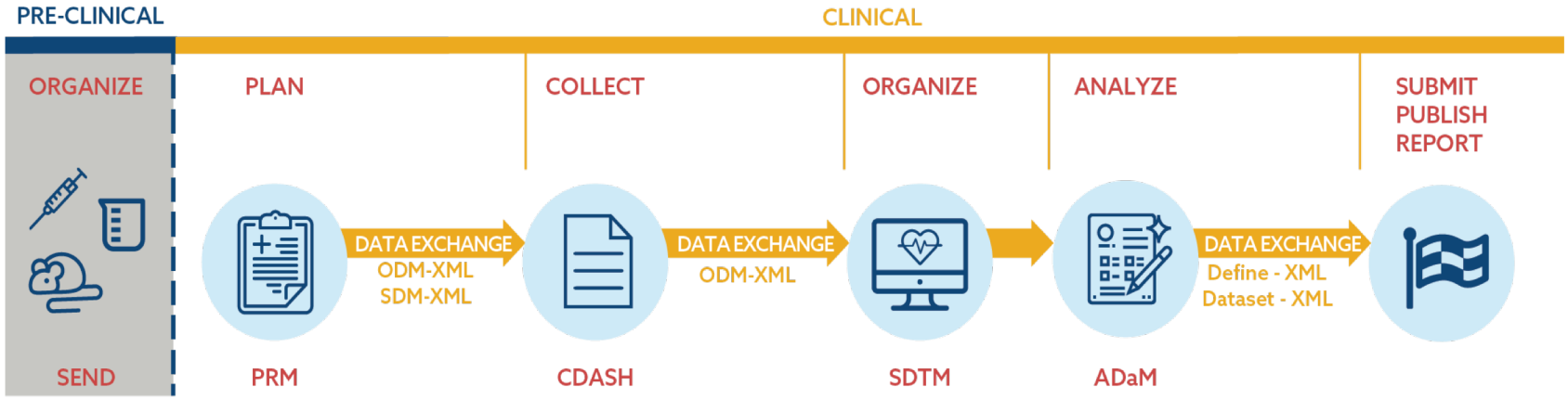
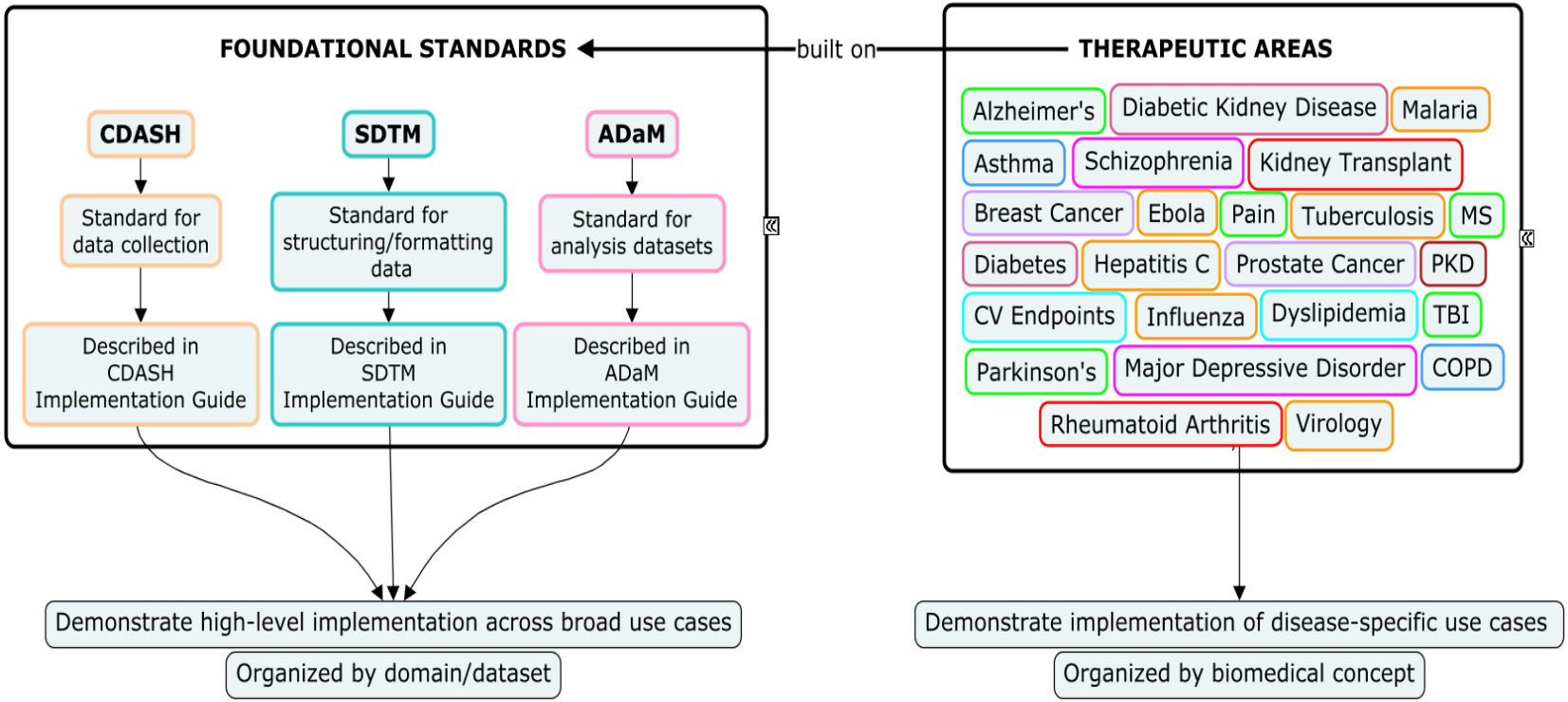
CDISC Standards in the Clinical Research Process



TAUGS

BRIDG, CONTROLLED TERMINOLOGY AND GLOSSARY

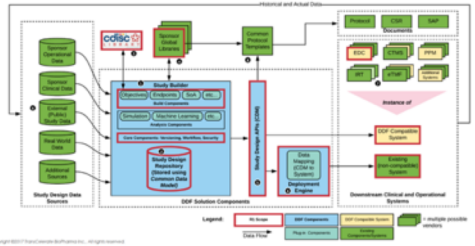
CDISC Standards



*The full list of foundational and therapeutic area standards are available at https://www.cdisc.org/standards

CDISC Library

Connect with Digital Data Processes through Open-API



Biomedical Concepts
Analysis Concepts
Templates

Codelist Subsets
TAUG metadata
Study design metadata

Tables, Listings, and Figures
Derivations and Mappings

Implementation Guide Text
Machine-readable Examples
CRF Collection

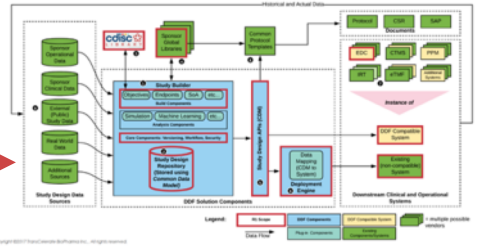
FHIR to CDISC Mappings
LOINC Code Mappings
Diff Content Between Versions

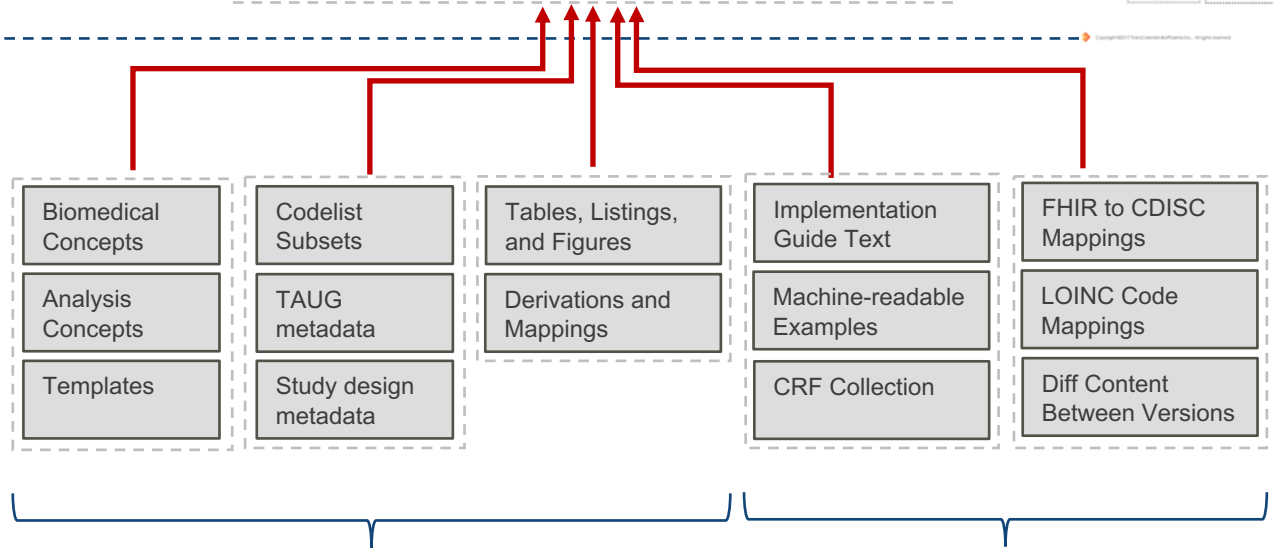
CDISC Standards

Informative Content

CDISC Library

Connect with Digital Data Processes through Open-API



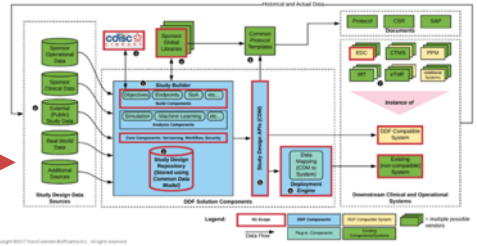


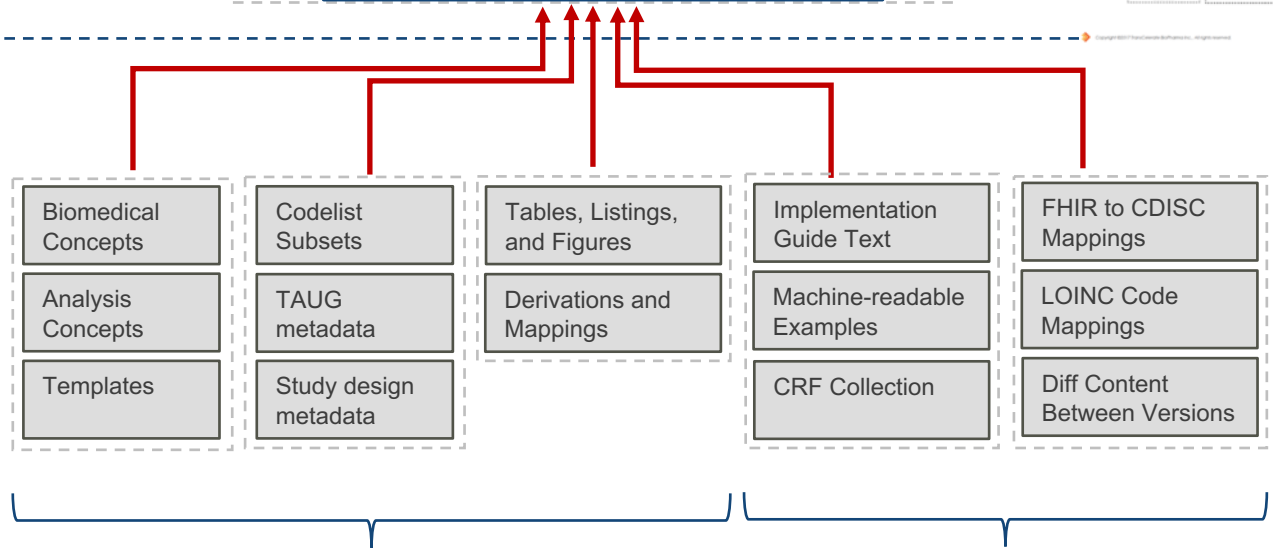
CDISC Standards

Informative Content

CDISC Library

Connect with Digital Data Processes through Open-API



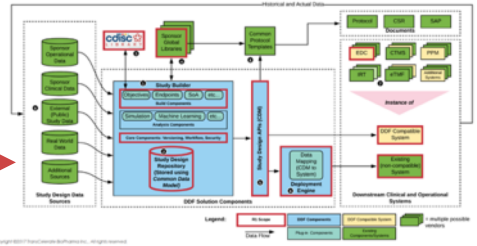


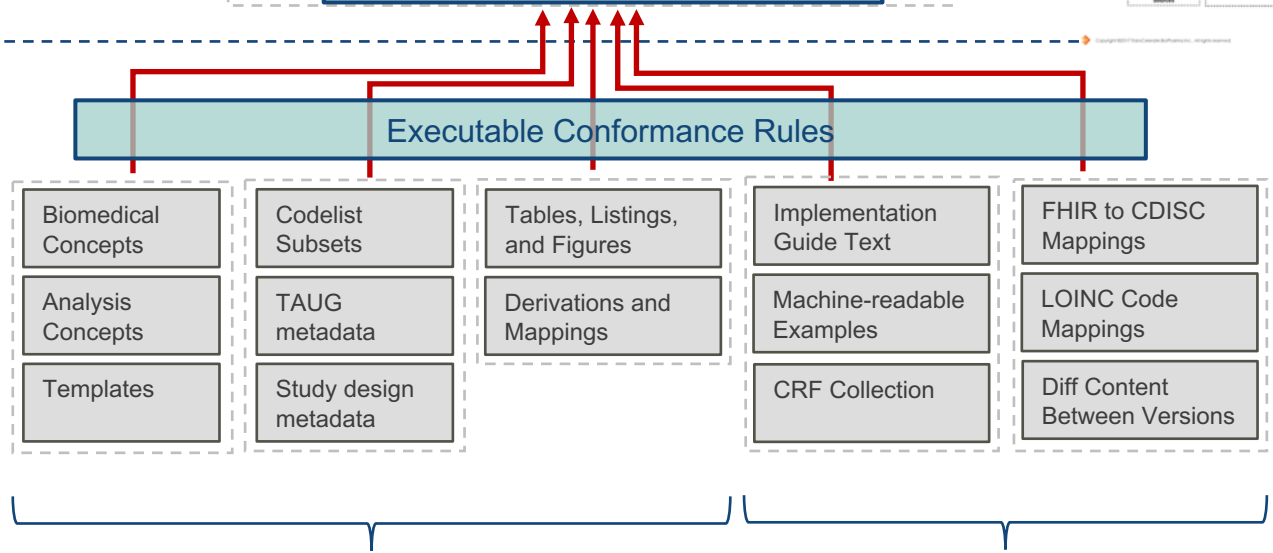
CDISC Standards

Informative Content

CDISC Library

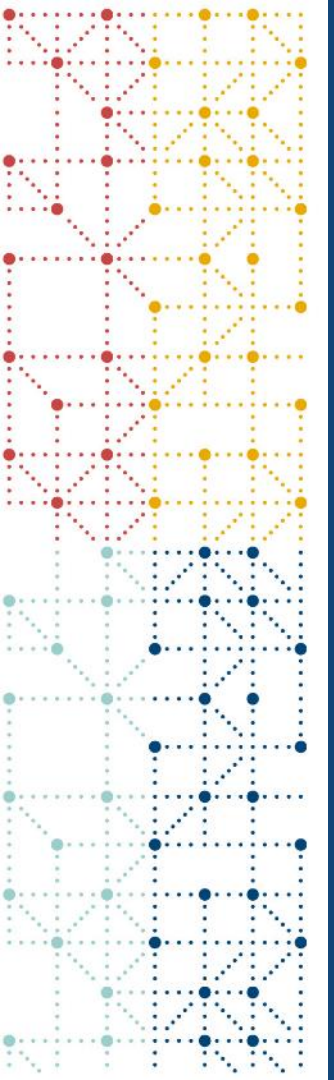
Connect with Digital Data Processes through Open-API



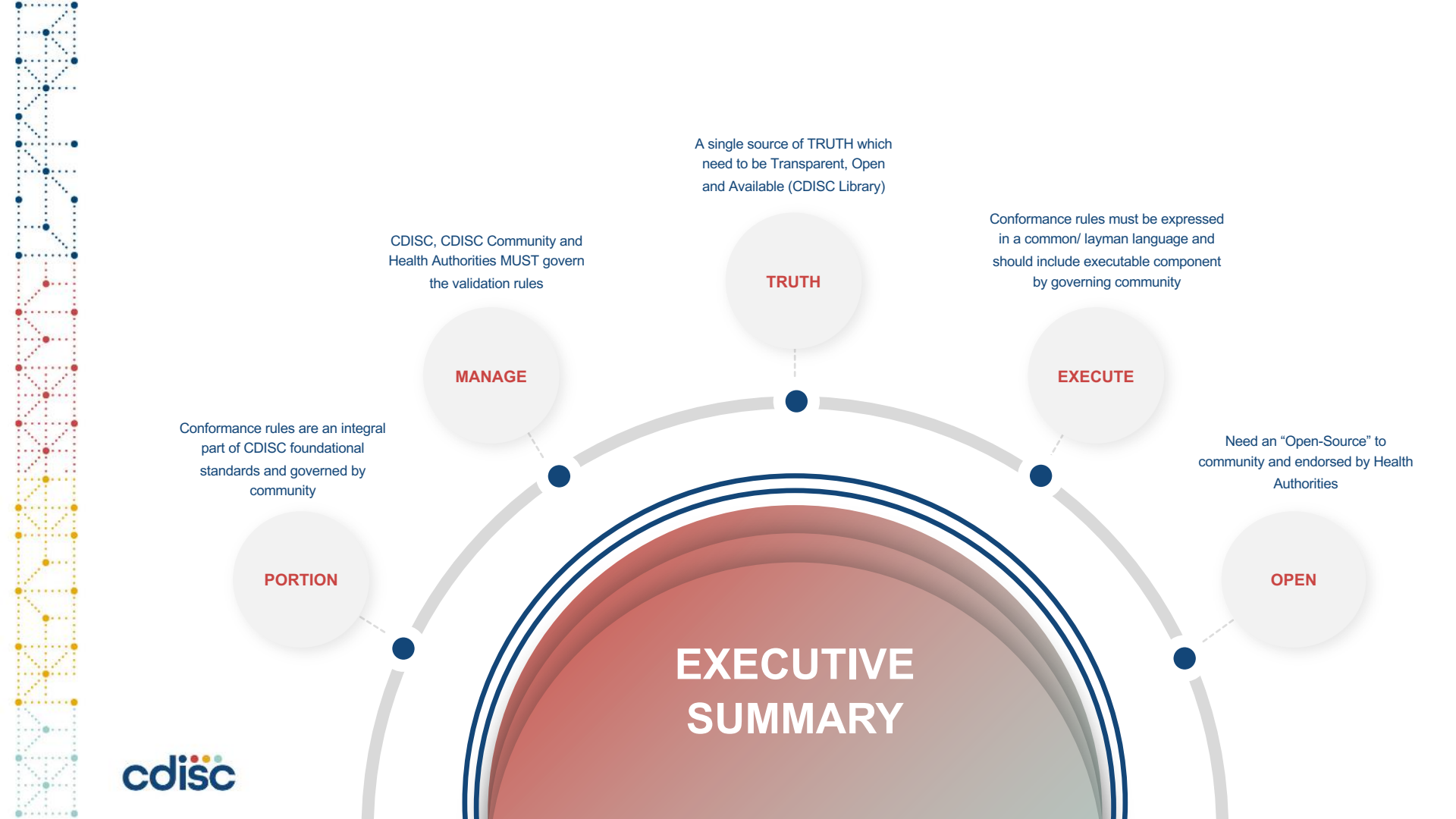


CDISC Standards

Informative Content



CORE Presentation


A single source of TRUTH which need to be Transparent, Open and Available (CDISC Library)
TRUTH
Conformance rules must be expressed in a common/ layman language and should include executable component by governing community
EXECUTE
Need an “Open-Source” to community and endorsed by Health Authorities
OPEN
Conformance rules are an integral part of CDISC foundational standards and governed by community
PORTION
CDISC, CDISC Community and Health Authorities MUST govern the validation rules
MANAGE
EXECUTIVE SUMMARY

1

COMMUNITY NEEDS

Golden Rules and one single TRUTH

2

INDUSTRY VISION

Integration with reporting environment

3

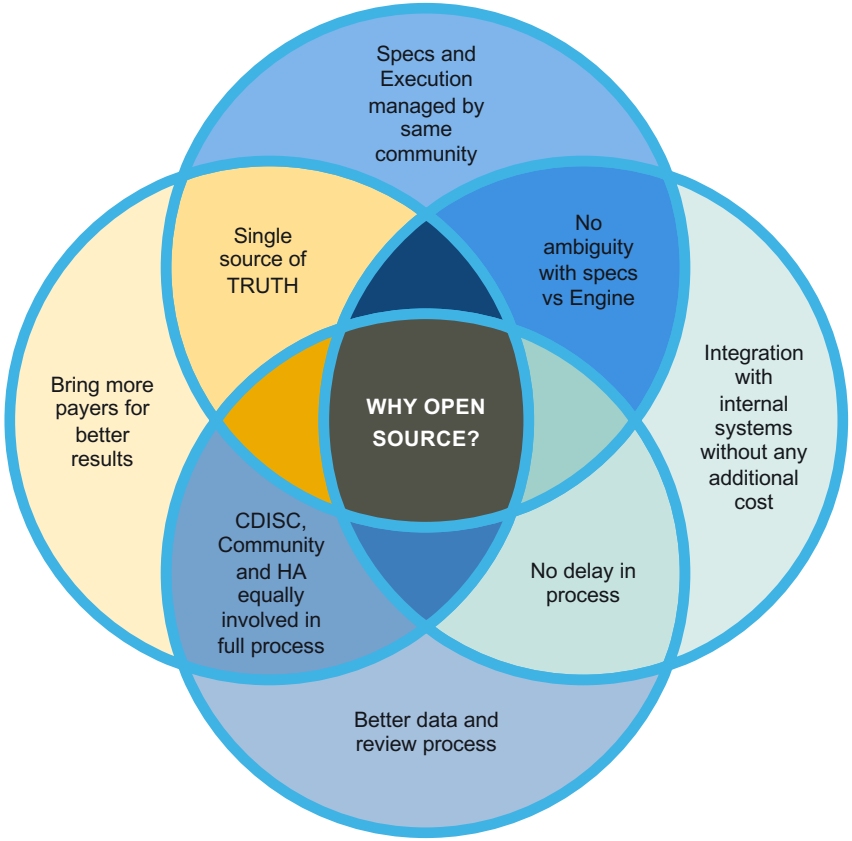
HEALTH AUTHORITY NEEDS

Data meets reviewer expectation

4

EXPECTED CAPABILITIES

Bring computation in this area by providing access executable validation engine support computation in user experience areas



CDISC CORE PROJECT

OBJECTIVE

- Each standard has a set of unambiguous, executable conformance rules
- Expedite the availability of executable conformance rules for new standards
- Ensure consistency across conformance rule implementations
- Create executable reference rules blessed by the CDISC standards team
- Publish conformance rules from the CDISC Library
- Create an open-source execution engine and publish under COSA
- The validation checks need to be released when new standard is available

SCOPE

- CORE will be released as open source under the MIT license
- Not offered by CDISC as a commercial product or service
- Executable rules - next step in the evolution of the conformance rules that CDISC publishes with every standard
- Executable rules published by CDISC should make it much easier for rule vendors to adapt these rules for use in their own software
- Existing rule vendors are free to contribute to or use the CORE engine software

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CORE – Further Considerations

- CORE will be released as open source under the MIT license
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- Executable rules - next step in the evolution of the conformance rules that CDISC publishes with every standard
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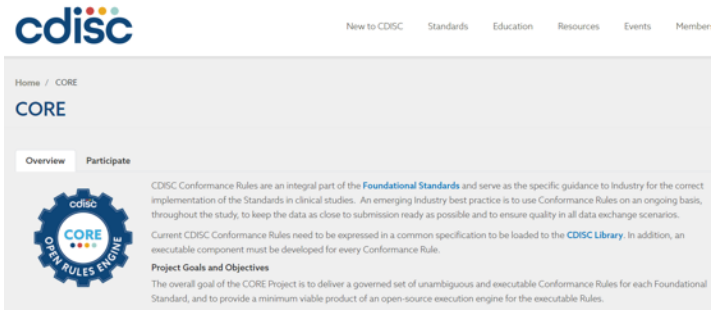
- https://www.cdisc.org/core



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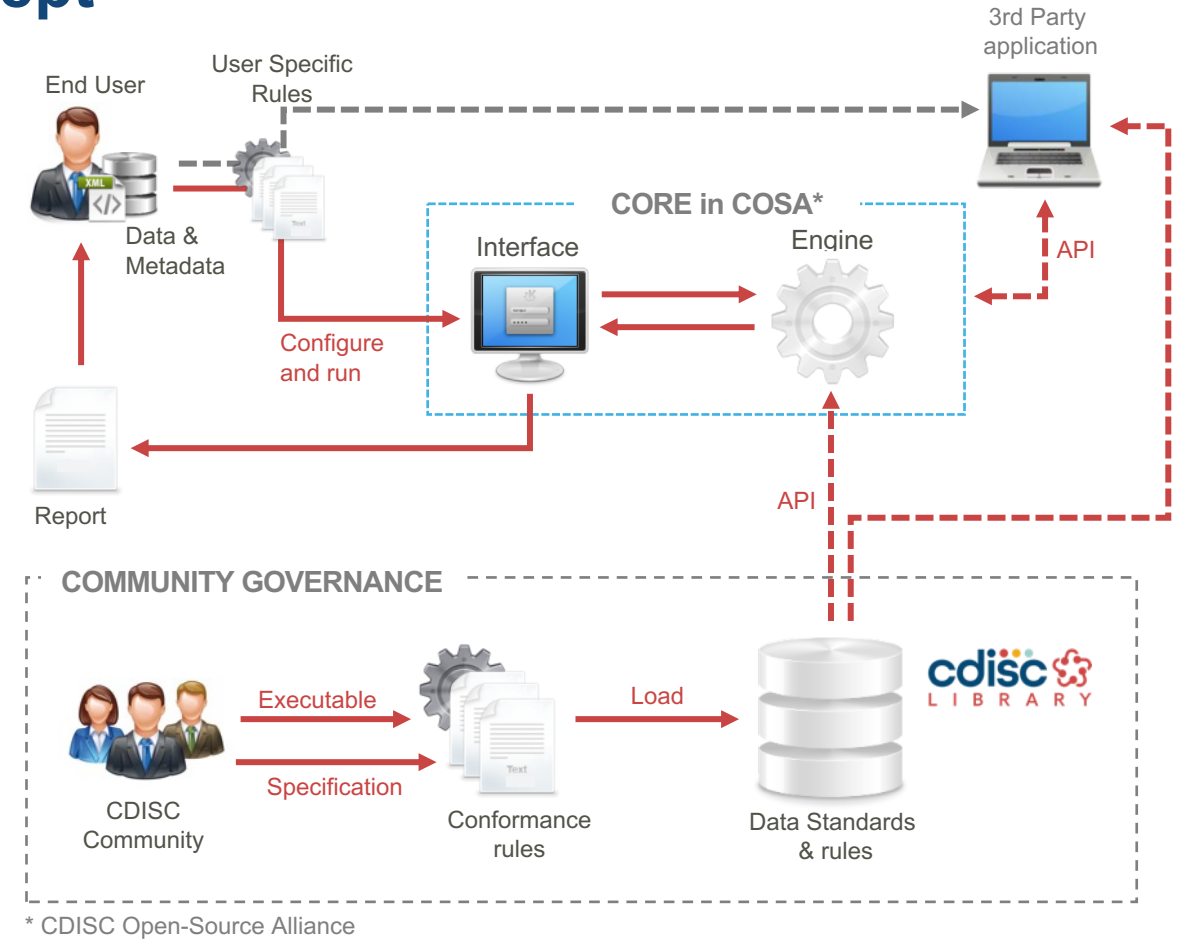
CORE Concept



* CDISC Open-Source Alliance

CORE Minimum Viable Product

- Roadmap calls for three releases: Minimum Viable Product, Release 1, Release 2
- Evaluation version – obtain feedback for future engine development
  - Align all CDISC Stakeholders on future release needs (Features, Technology, Timeline)
- Two deployment options
  - Easy and flexible evaluation options
  - Public and private cloud
- Conformance rules scope for MVP
  - SDTM 2.0 and SDTMIG 3.4
  - Does not exclude other (ADaM, SEND, Define.xml) but not critical for MVP

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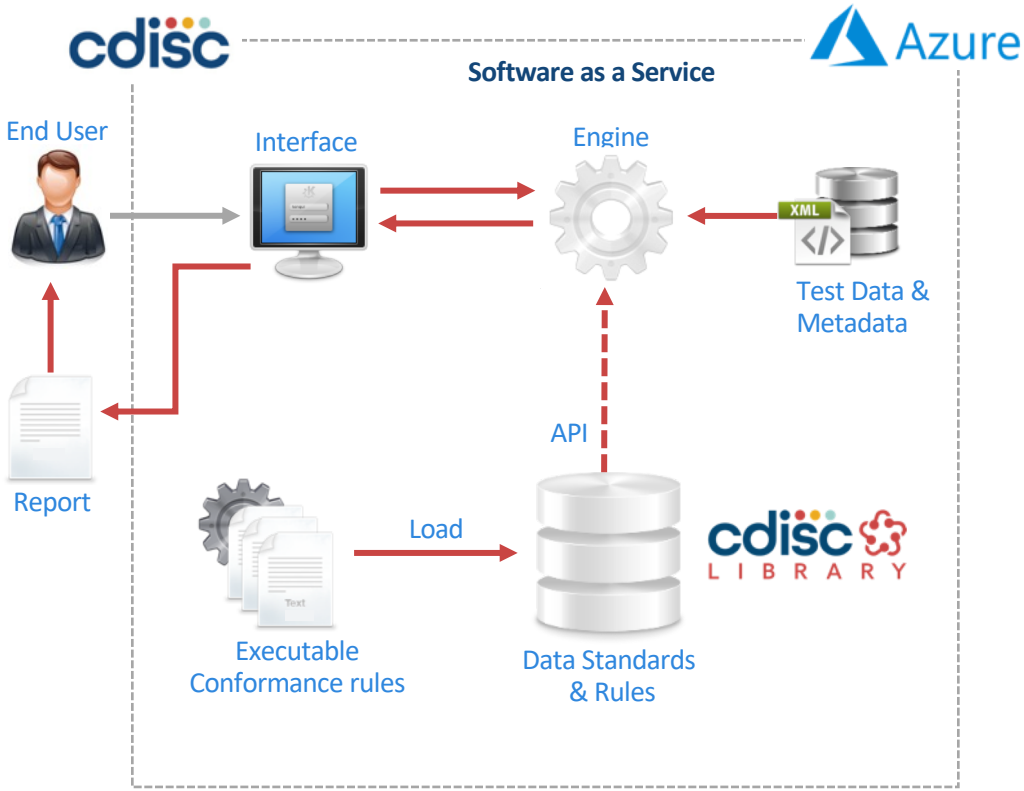
CDISC-Provided Cloud Evaluation Deployment

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
- CDISC seeks feedback from evaluators
- CDISC expects to update features, rules and test data during evaluation period

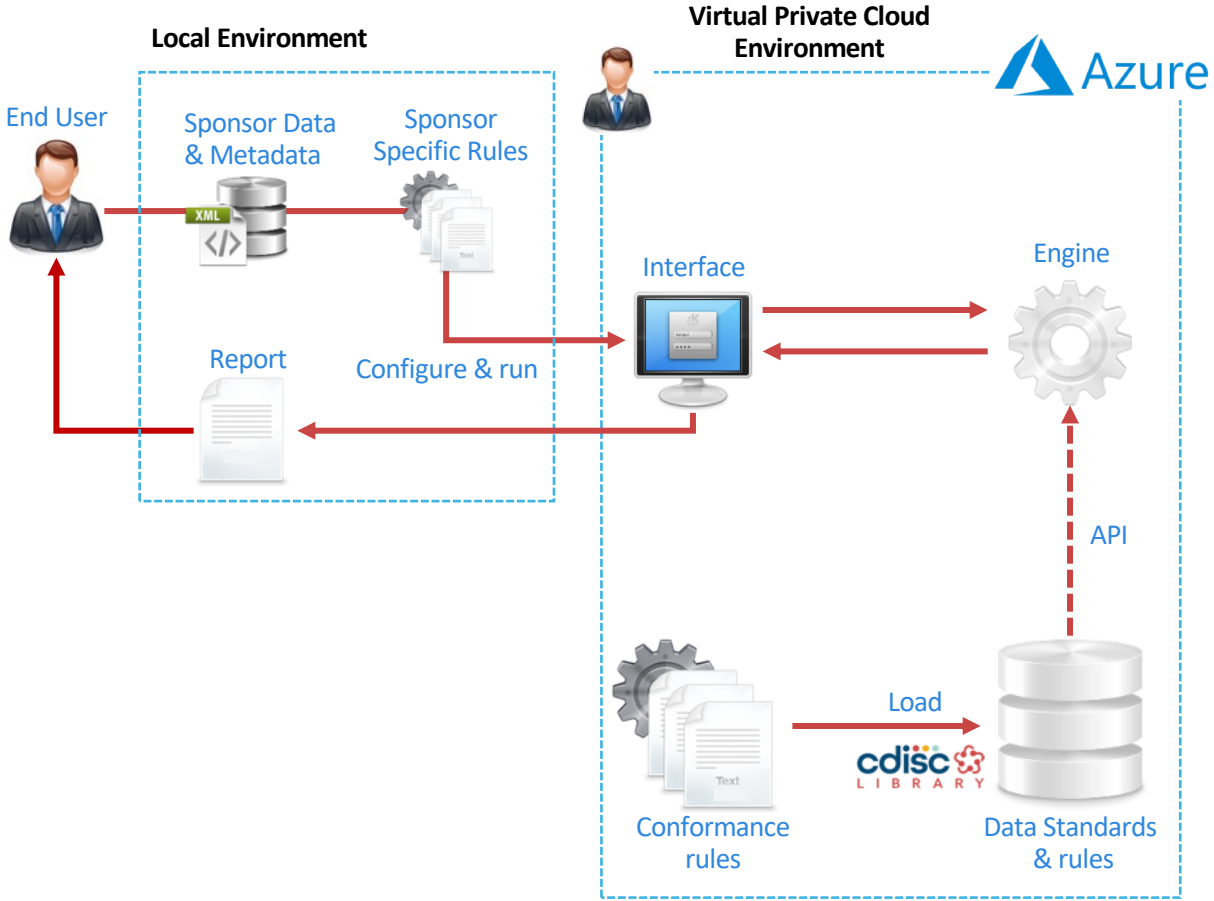


SaaS Evaluation Deployment Strategy

Virtual Private Cloud Evaluation Deployment

Deployment Attributes

- Private cloud environment
  - Some setup required
- A development version for user evaluation, released after the CDISC-provided cloud deployment
- 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
- CDISC seeks feedback from evaluators
- CDISC expects to update features, rules and test data during evaluation period



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CORE Program Roadmap

CDISC Vendor/User

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

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

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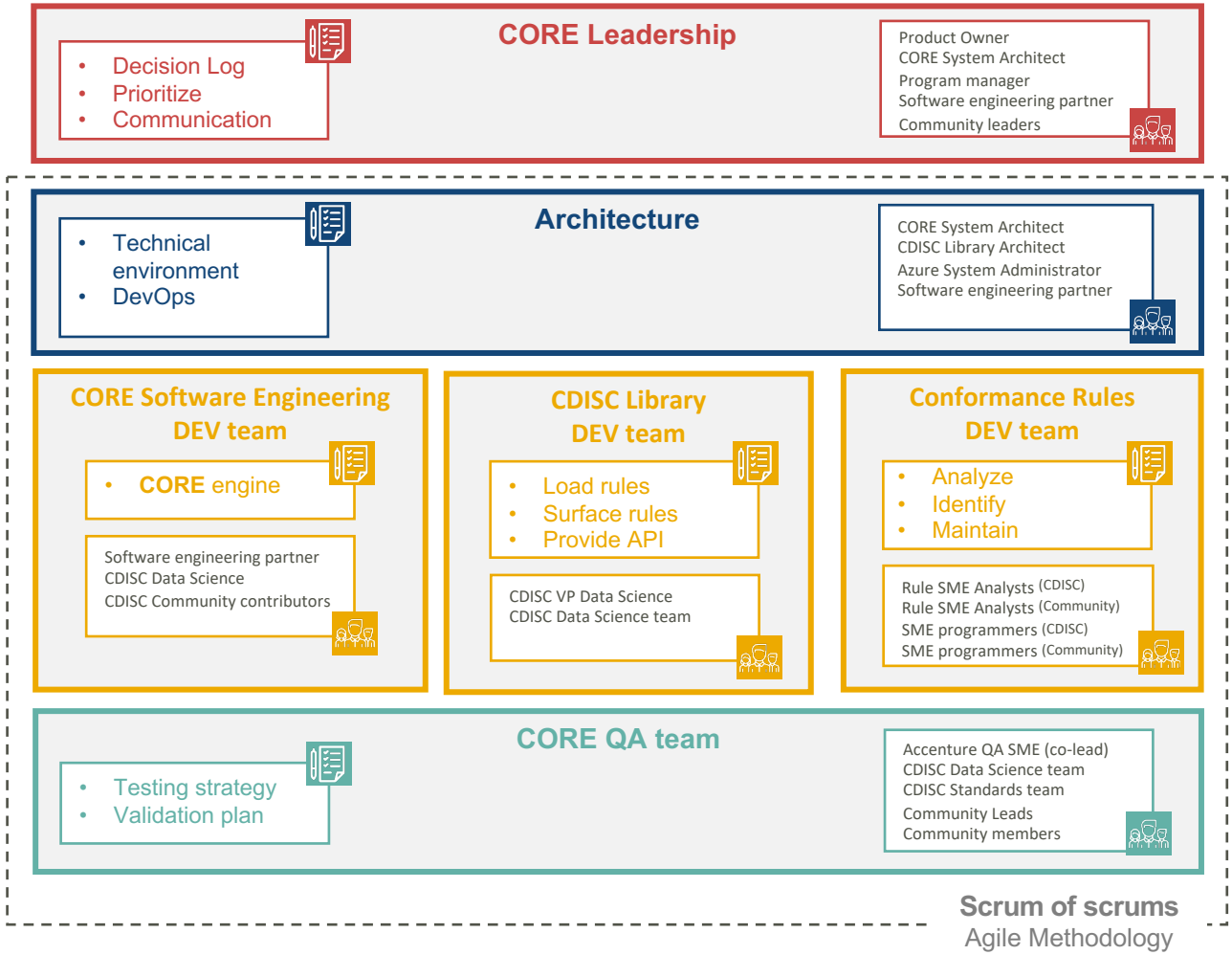
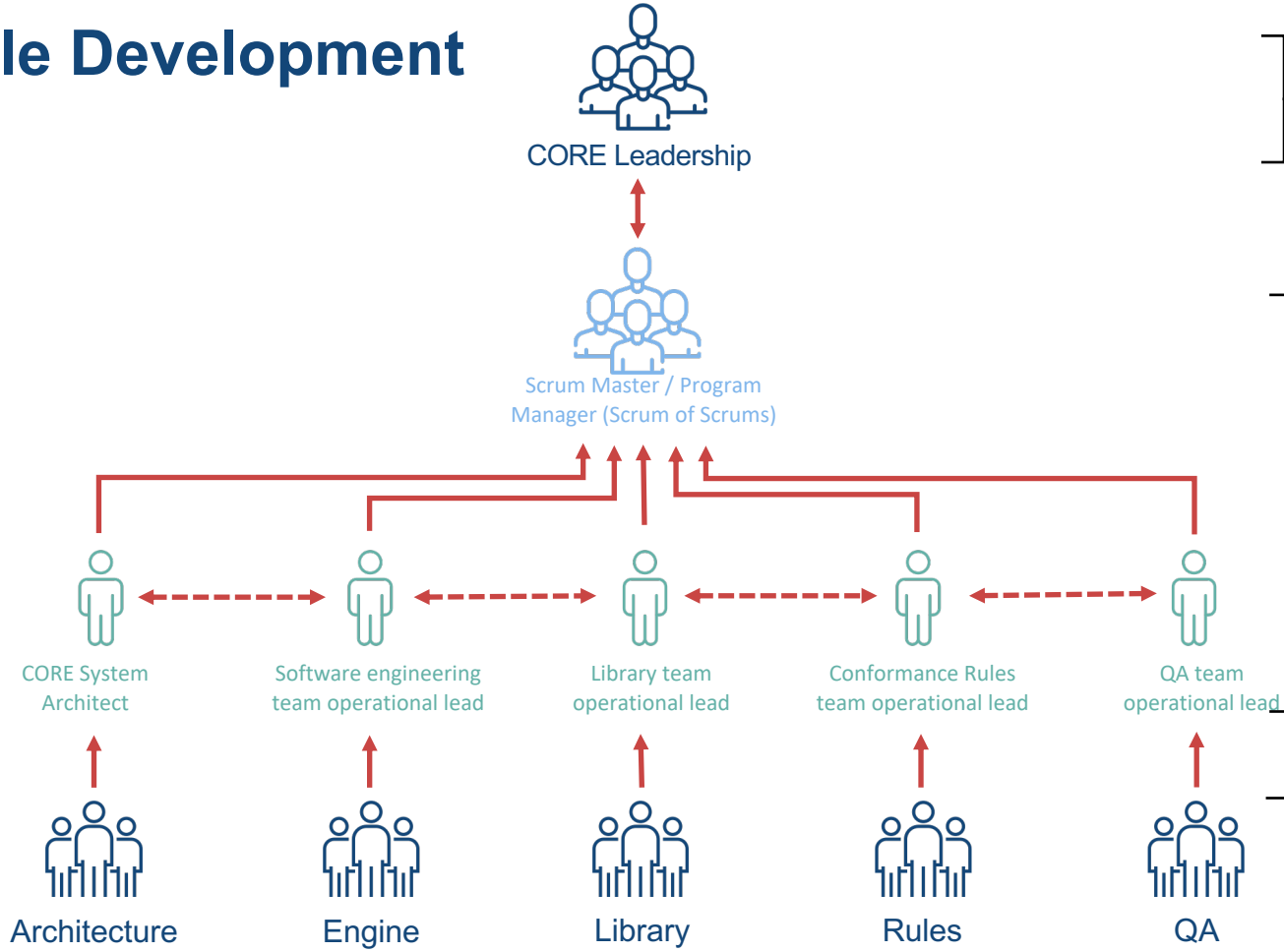
CORE team structure



Agile Development



CORE Leadership Meeting Cadence
- *Weekly*

Team Lead Meeting Cadence*
- *Backlog Grooming - weekly*
- *Scrum of Scrums – weekly*

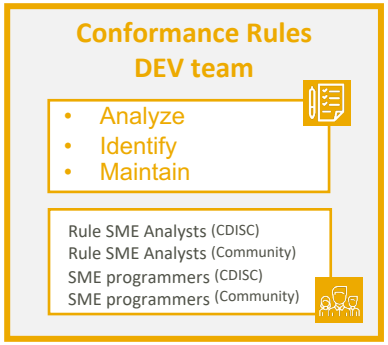
** Plus Team Member meetings*

Team Member Meeting Cadence

Architecture, Engineering & Library:
- *Scrum meeting - daily*
- *Sprint Review - fortnightly*

Rules & QA:
- *Team meeting - weekly*
- *Sprint Review - fortnightly*

Conformance Rules Development Team



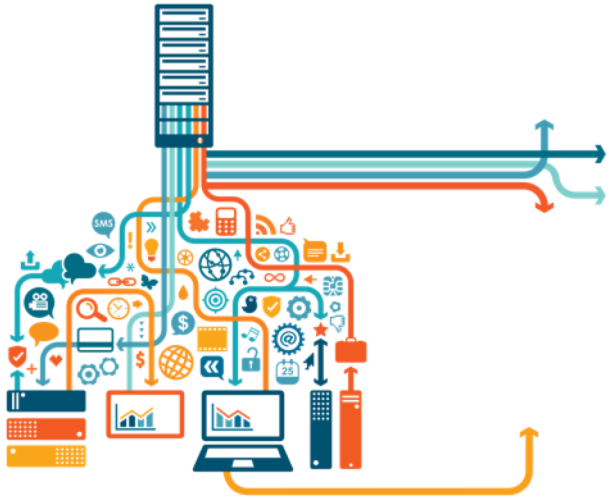
- Responsibility:
  - The rules' specification and the executable form of the rules
  - Executable rules development
    - Includes testing
    - Test Documentation
  - Feedback on Interface
  - Input in functionality
  - Conformance Rules Governance process

Executable rules will be metadata driven

Rule ID	SDTM IG Version	Rule Version	Class	Domain	Variable	Rule	Condition
CG0240	3.3	2	ALL	ALL	--TPT	--TPT and --TPTNUM have a one-to-one relationship	VISITNUM and --TPTREF are not present in dataset
Identifier		Version. Business Version	Constraint. Scope	Constraint. Scope	Input	Pre-process Expression	Constraint. Condition
			Needs disambiguation for shorthand "ALL".	Needs disambiguation for shorthand "ALL".			2 conditions exists in 1 statement. Written for human.

Conformance Rules Development Team

- MVP – focused on SDTM v2.0 and SDTMIG v3.4
  - Other rule sets for future releases, work will be ongoing
- Evaluate existing rules
  - Do they need revisions?
  - Are they testing what we expect them to test?
  - Assist QA team in evaluating rules
- Compile test data for evaluation
  - Positive and negative results
- Evaluate test data
  - Perform gap analysis
  - Augment test data as needed to accurately test rules



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Conformance Rules Development Team Roles

Standards SMEs	Provide interpretation & clarification from standards
	Consult for rule development experience
Conformance Rule SMEs	Consult for cross-foundational harmonization effort
	Consult for existing rule sets, such as disambiguation
Rule Developers	Create rules Manage changes, e.g., versioning, corrections
Test Data Developers	Create and manage test data to evaluate rules

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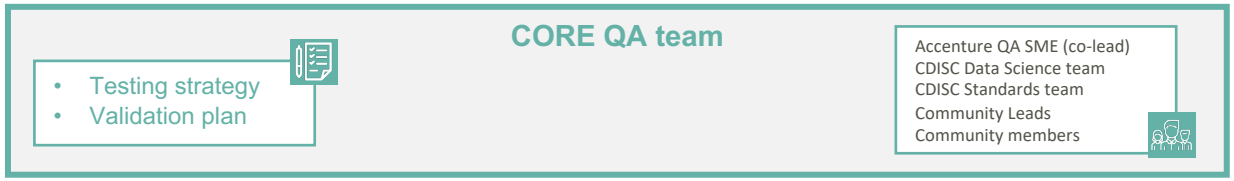
QA Team



- Responsibility:
  - Analysis and development of validation plan
  - Analysis and development of test data
  - Execution of validation plan
  - Execute Testing of Rules Logic
  - Execute testing of CORE engine for executable rules and test data
  - Report and analyze test results
  - Coordinate with Software Engineering DEV team on test results activities

- Membership:
  - Validation Lead
  - Validation SMEs and Testers
  - Technical Writers
  - Security Engineer (3rd party)

QA & Validation

- Project will follow CDISC Policies and Procedures that will include:
  - Quality Management
  - Software Development Lifecycle
  - Validation and Testing
  - Software Release and Support
  - Document and Artifact Management
- Regulatory-compliant validation approach assumption
- Validation and Testing will be accomplished for both CORE Engine and Rules
- Validation documentation package will be released as part of Open Source (COSA)
  - Artifacts for Development Validation released as part of MVP Phase
  - Artifacts for Deployment/Production Validation release as part of Release 1 and 2

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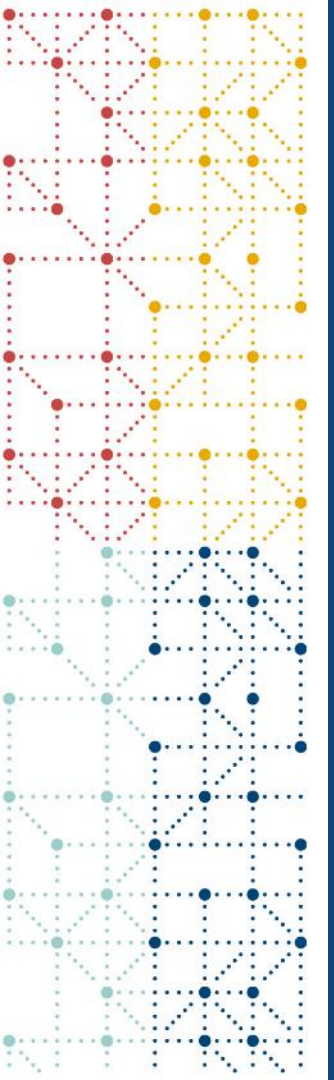
QA Team

- Develop and execute validation plan for rules Specification and executable form of rules
- Work areas:
  - Analysis and development of validation plan
  - Analysis and development of test data
  - Execution of validation plan
    - Execute testing of CORE engine
    - Execute testing of Rules logic
    - Report and analyze test results
    - Coordinate with Software Engineering DEV team on test results activities and remediations
- Team members:
  - Validation Lead
  - Validation SMEs and Testers
  - Technical Writers
  - Security Engineer (3rd party)

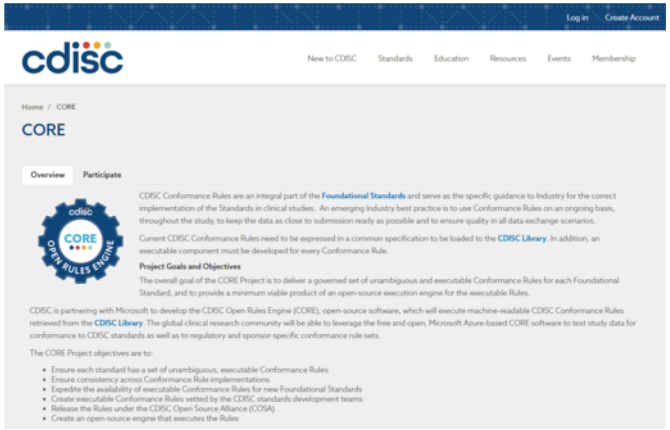


Call for Participation

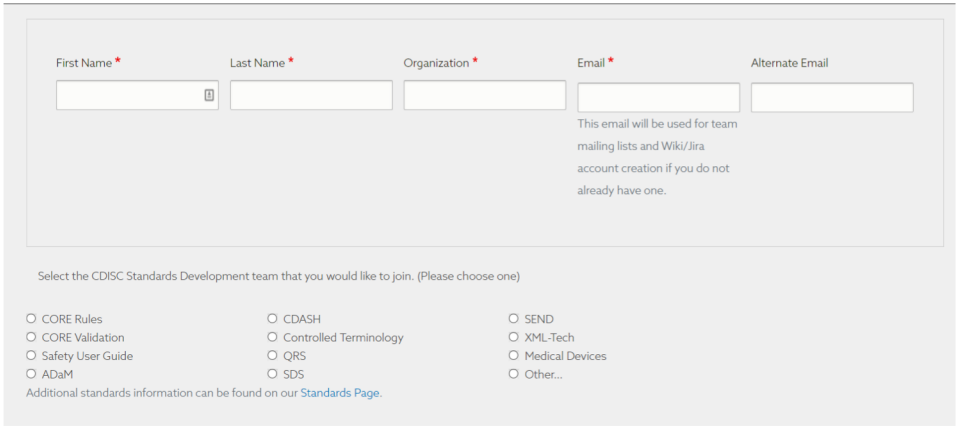
Call for Industry Participation

- Project execution period for MVP
  - 2021 Q3 – 2022 Q1 (about 9 months)
- Expected FTE level
  - Minimum 20%
- Kickoff meeting planned for Sept 9, 2021
  - Save the date!

Sign Up



https://www.cdisc.org/core



https://www.cdisc.org/volunteer/form

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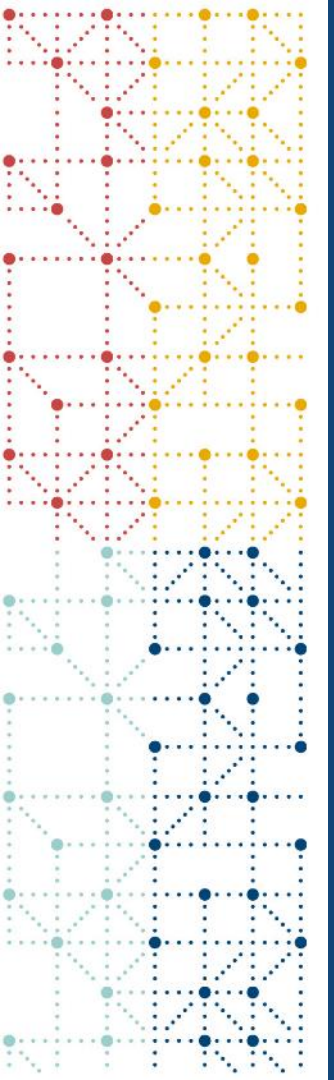


Questions & Answers

Audience Questions

What format will the reports be created in?

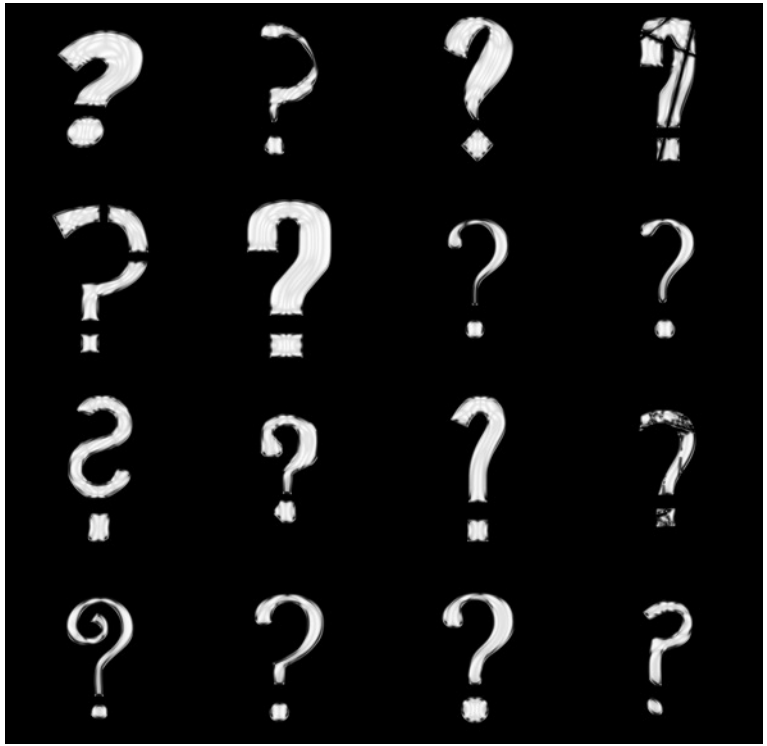
Audience Questions

What programming language will be able to execute CORE rules?

Audience Questions

How can CORE integrate with third party tools and applications?

Audience Questions



Is this an open-source initiative to enable automation of the standards processes using the CDISC Library standards metadata?

Audience Questions

How will you ensure the sustainability of this open-source project?

Audience Questions

Will the regulatory agencies adopt the CORE rules?

Audience Questions

How will CDISC work with vendors in this space?

Audience Questions

Peter:

How would these conformance rules differ from already existing applications/vendors?

Audience Questions

When the CORE conformance checks are configured completely after the end of the project, does CDISC also liaise with FDA, PMDA and NMPA?

Audience Questions

When will CORE released?

Audience Questions

How will the engine be able to run in the cloud, but have the data remaining locally?

Audience Questions

Is there a planned feedback and development cycle for the ruleset to progress hand-in-hand with the CORE initiative?

Audience Questions

What's the timeline for users be able to configure customized rules?

Audience Questions

How will conformance rules be configured (a language, metadata, etc.)?

Audience Questions

Do CDISC executable rules take into account the agency-specific rules from technical conformance guides and/or Technical Rejection Criteria and if so, will agency rules supersede the CDISC rules in case of differing opinion(s)?

Upcoming Learning Opportunities

New Virtual Training Methods

- Information available at: www.cdisc.org
- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org

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2021 CHINA INTERCHANGE

With Standards – Science Will Prevail!

Beijing | 6-7 August

Conference | Trade Show

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2021 US INTERCHANGE

With Standards – Science Will Prevail!

Washington, DC, or Virtually | 18-22 October | Conference & Trade Show

Thank you!

Contact the Events inbox:
events@cdisc.org

Contact general EDU inbox:
training@cdisc.org

Contact Bernard directly:
bklinke@cdisc.org