2021 US INTERCHANGE

With Standards – Science Will Prevail!

Conference | Trade Show

Virtual Event | 20-21 October

CDISC Open Rules Engine (CORE)

Peter Van Reusel, Chief Standards Officer, CDISC
Sam Hume, DSc, VP Data Sciences, 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.

Meet the Speaker

Sam Hume

Title: VP, Data Science

Organization: CDISC

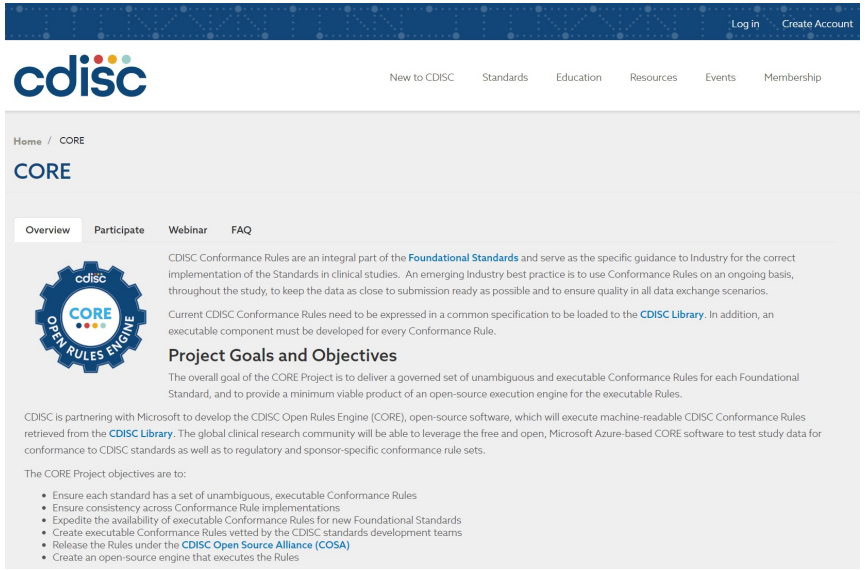
Sam Hume leads the CDISC Data Science team, which collaborates with CDISC staff and stakeholders to develop tools and standards that support clinical and translational data science. Sam directs delivery of the CDISC Library metadata repository that houses all CDISC standards, co-leads the CDISC Data Exchange Standards team, and leads the technical CDISC RWD efforts. He has 25 years' experience in clinical research informatics and has held a number of senior technology positions in the biopharmaceutical industry. He holds a doctorate in information systems.

Agenda

1. CORE Overview
2. CORE Project Approach
3. CORE Project Status

CORE Overview

CORE Goals and Objectives



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CORE

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CDISC Conformance Rules are an integral part of the **Foundational Standards** and serve as the specific guidance to Industry for the correct implementation of the Standards in clinical studies. An emerging Industry best practice is to use Conformance Rules on an ongoing basis, throughout the study, to keep the data as close to submission ready as possible and to ensure quality in all data exchange scenarios.

Current CDISC Conformance Rules need to be expressed in a common specification to be loaded to the **CDISC Library**. In addition, an executable component must be developed for every Conformance Rule.

Project Goals and Objectives

The overall goal of the CORE Project is to deliver a governed set of unambiguous and executable Conformance Rules for each Foundational Standard, and to provide a minimum viable product of an open-source execution engine for the executable Rules.

CDISC is partnering with Microsoft to develop the CDISC Open Rules Engine (CORE), open-source software, which will execute machine-readable CDISC Conformance Rules retrieved from the **CDISC Library**. The global clinical research community will be able to leverage the free and open, Microsoft Azure-based CORE software to test study data for conformance to CDISC standards as well as to regulatory and sponsor-specific conformance rule sets.

The CORE Project objectives are to:

- 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

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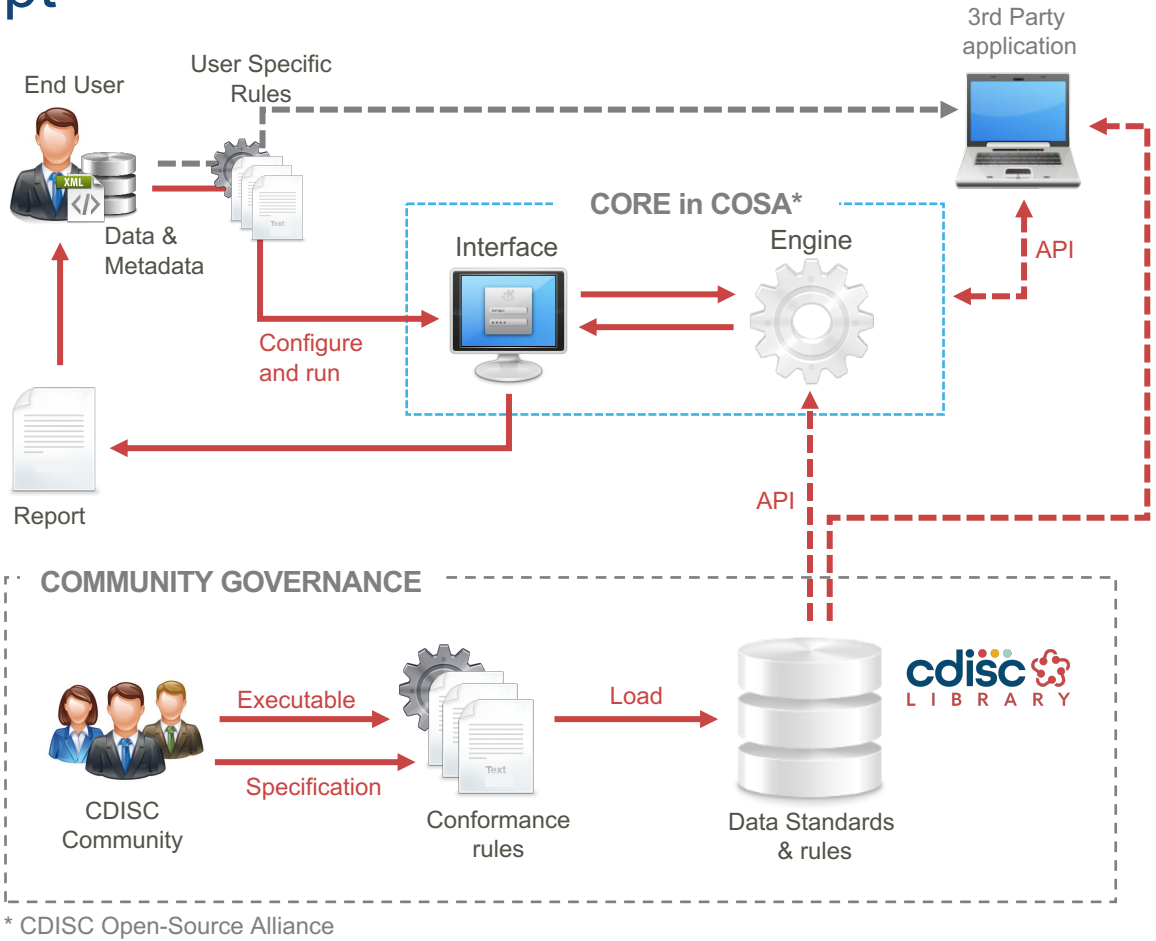
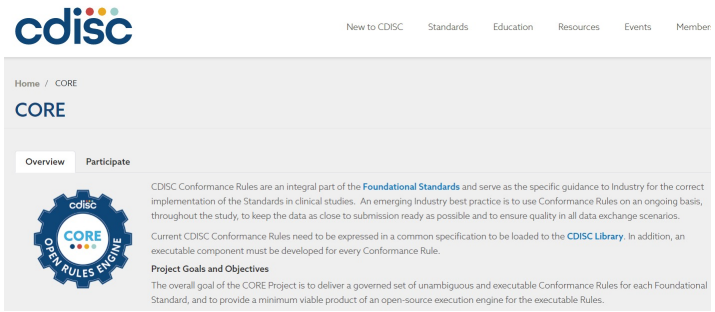
CORE Concept



* CDISC Open-Source Alliance

CORE – Further Considerations

- 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
- https://www.cdisc.org/core



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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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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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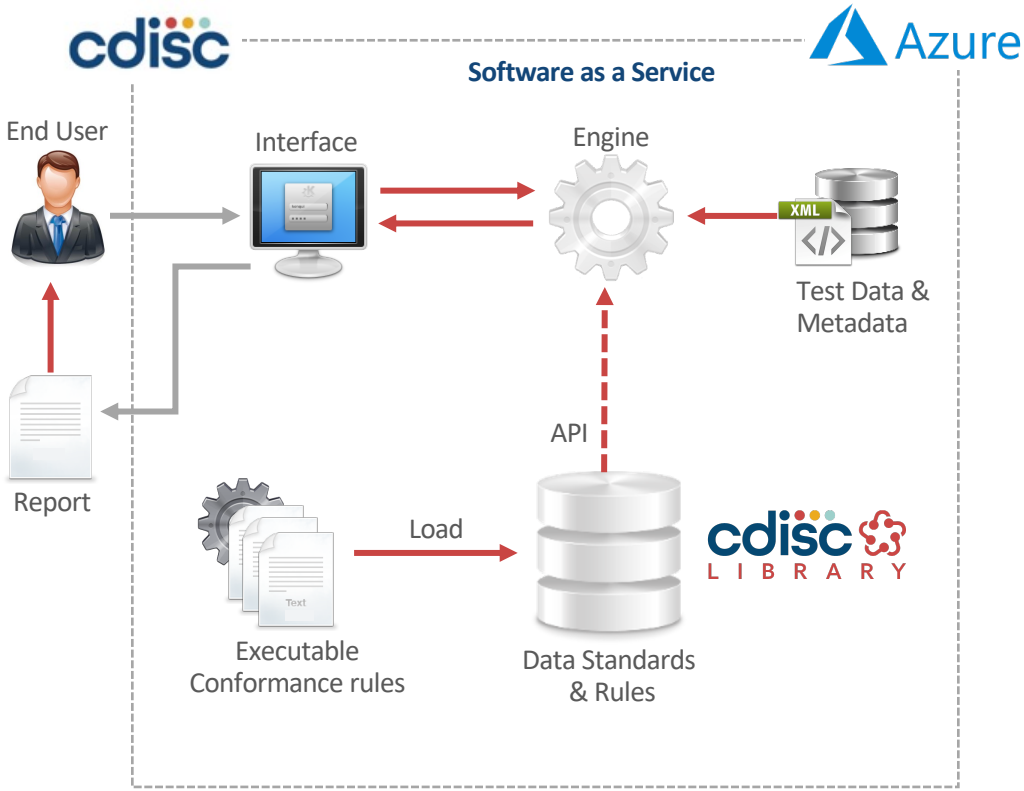
CDISC-Provided Cloud Evaluation Deployment

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

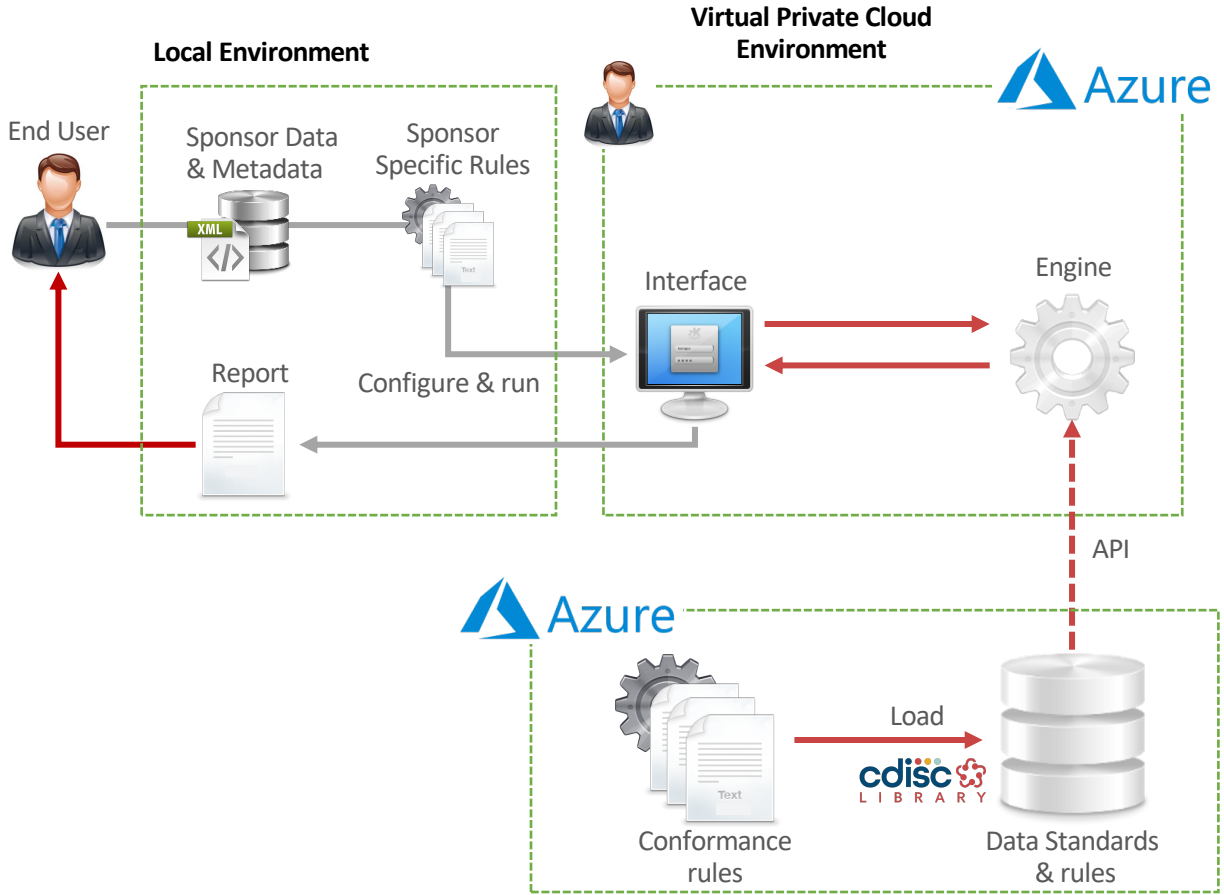


SaaS Evaluation Deployment Strategy

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

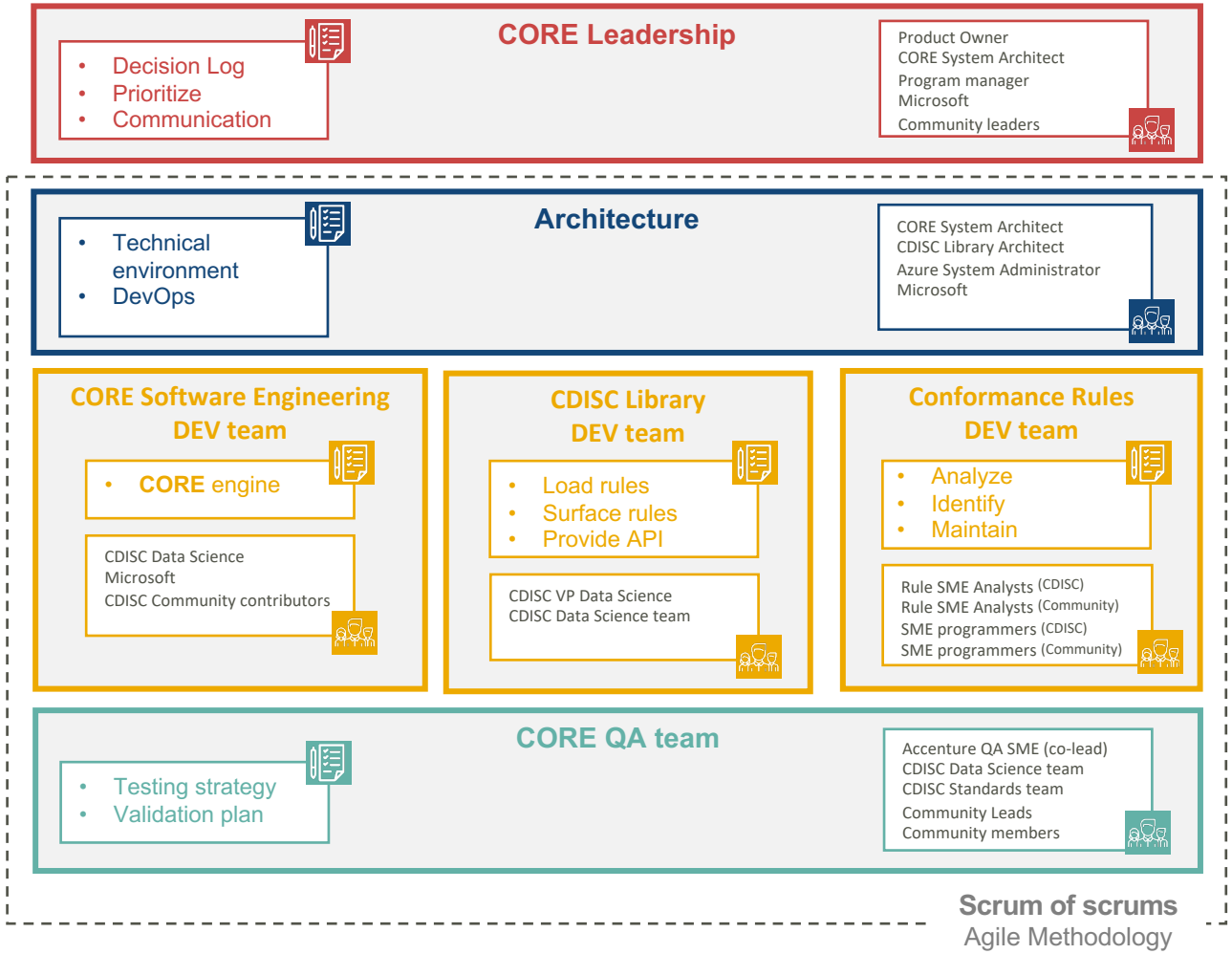


CORE Project Approach

SGS Health Science

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

CORE team structure



CORE team Members

CORE Leadership

- Peter Van Reusel
- Sam Hume
- Charles Shadle
- Nick De Donder
- Anne-Sophie Bekx
- Venkata Maguluri
- Stephen Matteson
- Tianna Umann
- Michael Topp
- Kim Mattox Jr.

Architecture

Anthony Chow
Sam Hume
Tarun Khurana
David Crawford
Tianna Umann
Mallikharjuna Rao Satyavolu

CORE Software Engineering DEV team

- Jim Blanchard
- Satyandra Vishwakarma
- Aman Sextus
- Vivek Kumar
- Siqi Liu
- Ankita Kumari
- Shachi Panday
- Dmitry Kolosov
- Nic Haydel
- Gerry Campion
- Nick De Donder
- Drew Mills

CDISC Library DEV team

- Anthony Chow
- Nic Haydel
- Gerry Campion
- Omar Garcia Calderon

Conformance Rules DEV team

Next Slide

CORE QA team

- Dan Li
- Jagruti Patel
- Jinkyu Lee
- John McDade
- Mike Heenan
- Narasimhan Kaliyamoorthy
- Nikhil Upadhyay
- Sangeeta Sama
- Shaun Maraj
- Shaveta Bansal
- Haiping Yu
- Hanumanta Kavuluru
- Gleb Strus
- Aleksei Culei

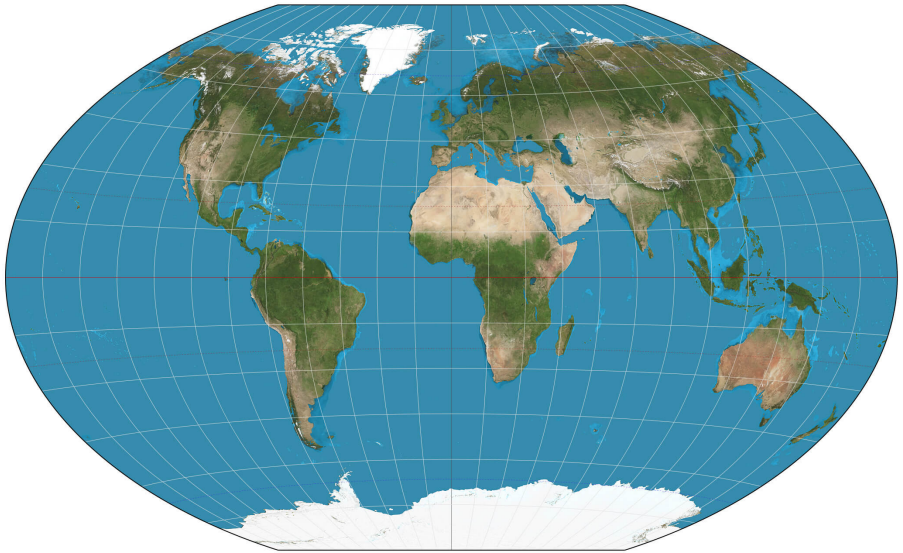
CORE team Members Cont'd

Conformance Rules
DEV team

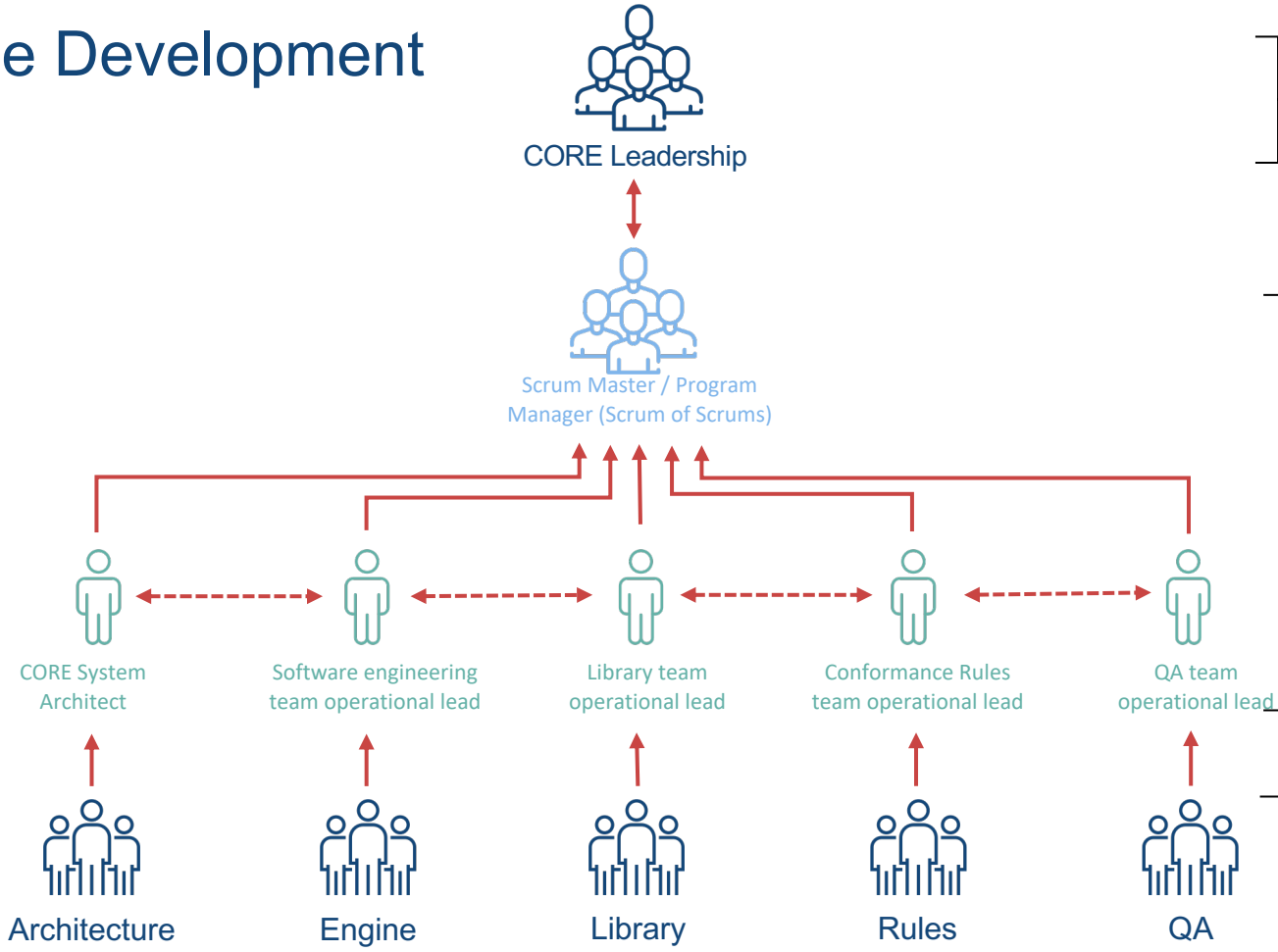
- Abdulkadir Lokhandvala
- Ajay Gupta
- Amy Garrett
- Anne Barsanti
- Beilei Xu
- Bhavin Busa
- Carlo Radovsky
- Chao Wang
- Cindy Dulaney
- David Wang
- Dhananjay Thakur
- Elisa Young
- Els Janssens
- Gauravbir Dogra
- Jackie McGuirk
- Jacques Lanoue
- Joseph Rajan
- Joy Victor
- Jundong Ma
- Kim Mattox
- Kristin Kelly
- Lyubov Sushchenko
- Malini Narreddy
- Mandar Oak
- Mark Aellen-Rumo
- Maurits Meijboom
- Michelle Lumicao
- Mohammed Khan
- Naila Musani
- Nikola Cihoric
- Rama Balakrishnan
- Ryan Burns
- Stetson Line
- Suraiya Khan
- Torsten Petsching
- Wei Wang
- Jacqueline McGuirk
- Tedis Agolli
- Jaehoon Kwon
- Rajprakash Chennamaneni
- JungHyun Kim
- Steve Fizpatrick
- Marisa Wyckmans

Volunteer participation

- Very active volunteers
  - Many 1st time CDISC Volunteers
  - > 50 team members
  - Adding new team members weekly
- Project started July
- Volunteer teams began meeting weekly mid-September



Agile Development



CORE Leadership Meeting Cadence
- *Weekly*

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

** Plus Team Member meetings*

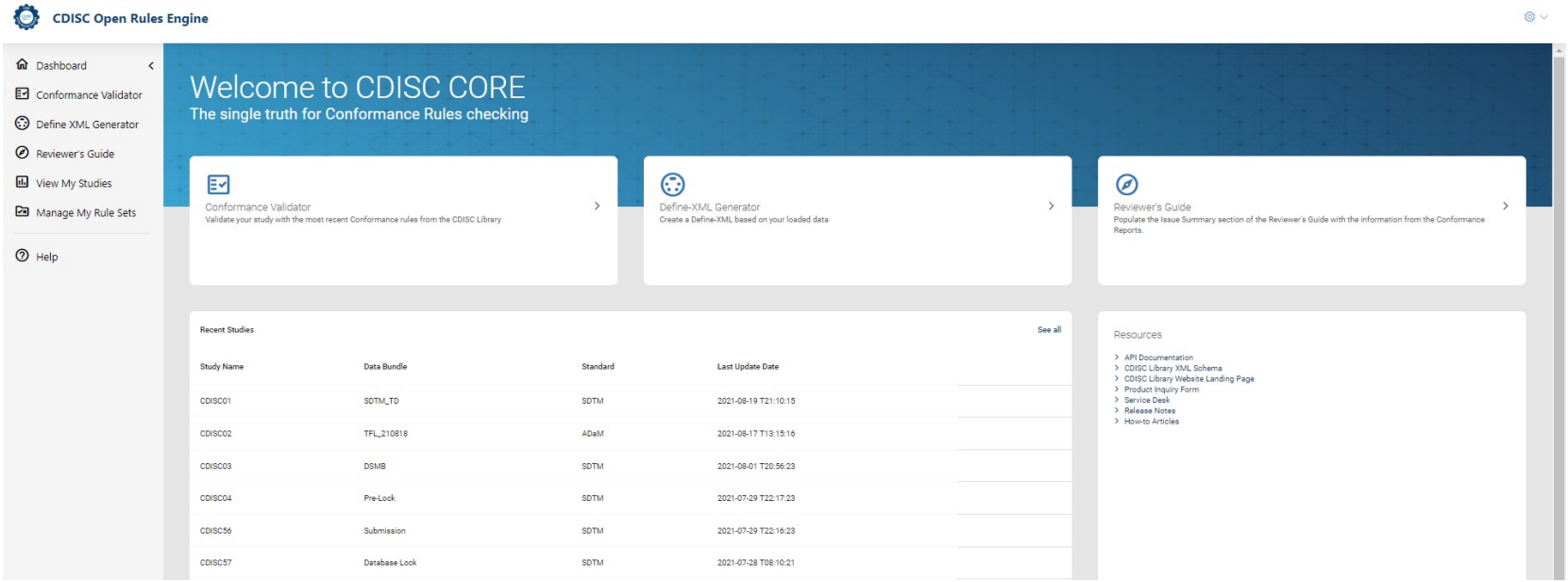
Team Member Meeting Cadence

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

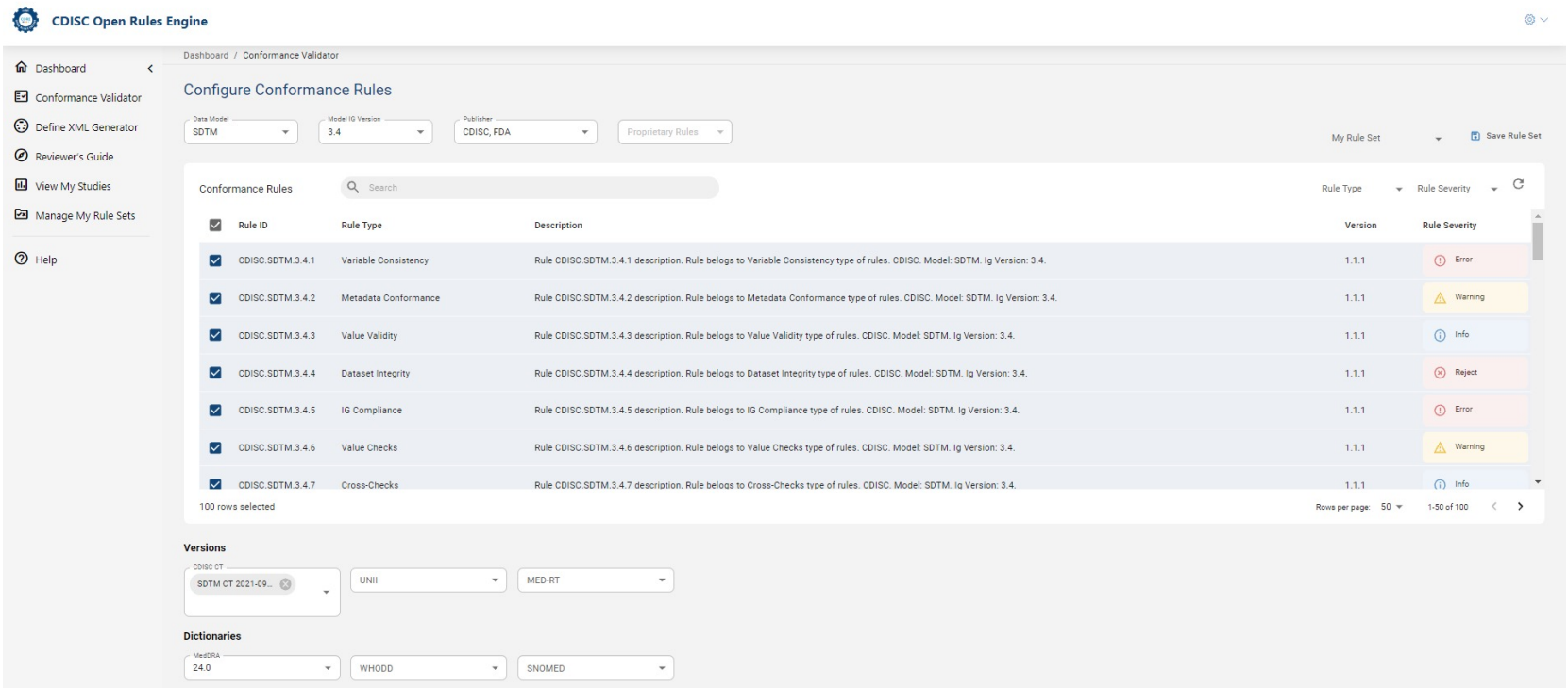
Rules & QA:
- *Team meeting - weekly*
- *Sprint Review - fortnightly*

CORE Project Status

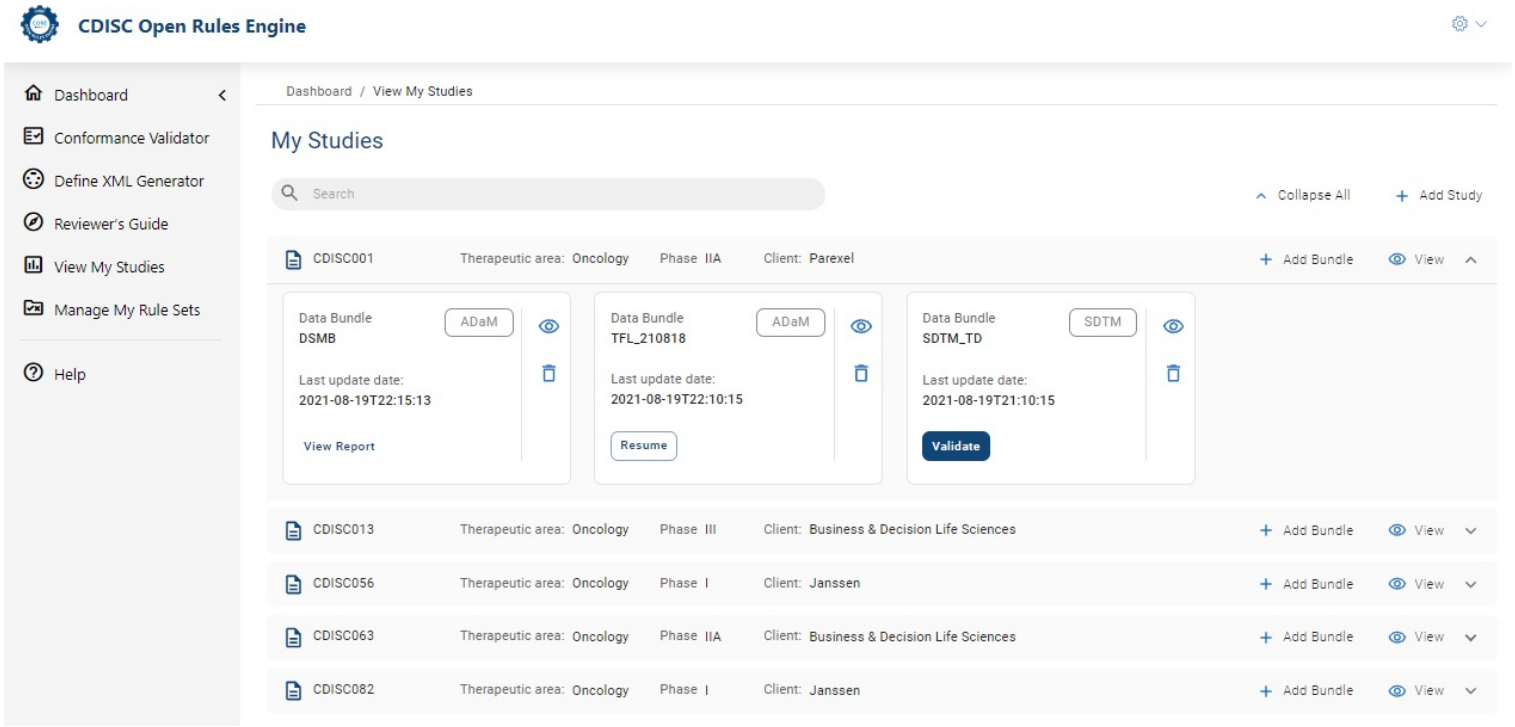
UX/UI: CORE Dashboard



UX/UI: Conformance Validator



UX/UI: Study Management



Metadata components

- Rule identifiers
  - CoreId, Version, Status, …
- Authority
  - Organization, RuleId, …
- Scope
  - Standards & Version, Classes, Domains, …
- Rule
  - Dependency, Type, Condition, …
- Outcome
  - Message
- Citations
  - Document, Section, Item, Cited Guidance

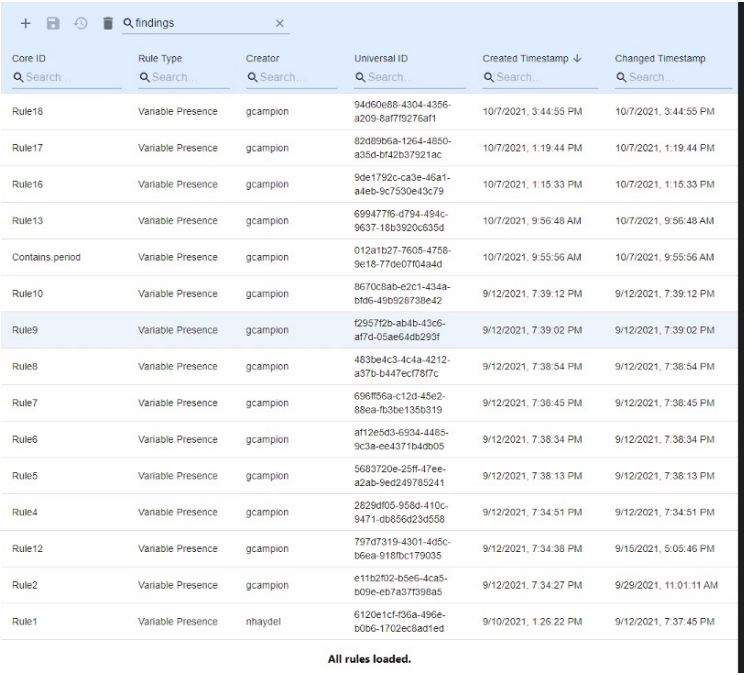
Benefits

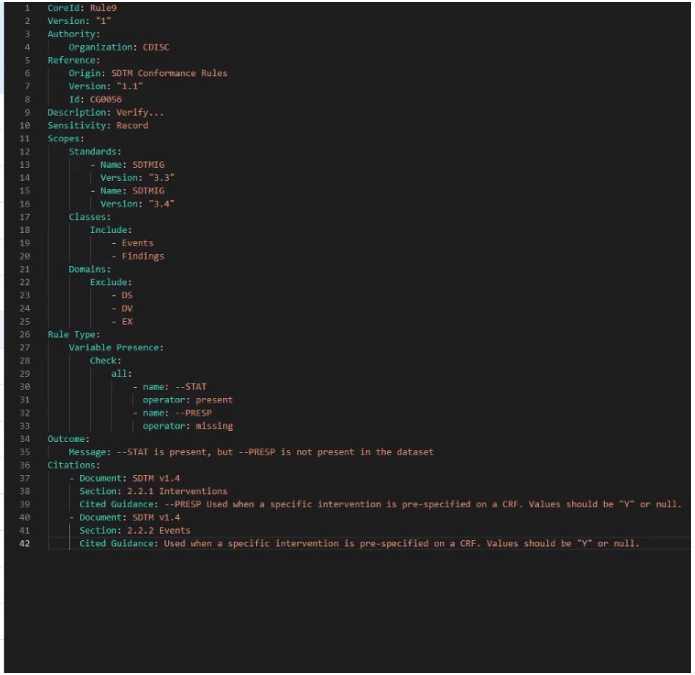
- Explicit rule logic
- Common expression & syntax
- Information about each rule
- “Hints” to optimize runtime performance

Notes

- Do expect continuous refinement

CORE Rule Editor





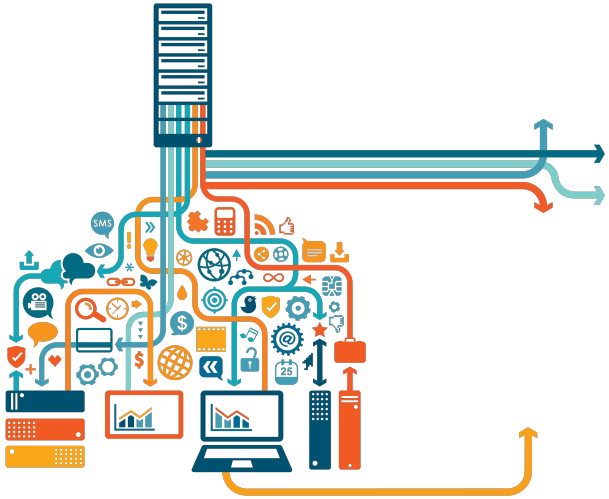
- Web-based application, no software to install
- Structured document, 1 CORE rule per file containing rule's metadata & check logic
- Real-time syntax checking

CORE Rule Authoring

- Employs a no- & low-code configuration approach
- Emphasizes on explicit metadata, such as versioning, scoping, applicable standards, etc.
- Supports multiple rule types: Value presence, value comparison, data pattern & matching, etc.
- Rule authoring guide and supporting documentations are being maintained as new capabilities are added
- Coming soon: Rule testing to verify logic using positive & negative test data

Rule Development Process

- Evaluate existing rules
  - Do they need revisions?
  - Are they testing what we expect them to test?
  - Assist QA team in evaluating rules
  - Scope includes both rule specification and executable version of rule
- Identify missing rules
- Evaluate existing test data
  - Perform gap analysis
  - Augment test data as needed to accurately test rules
- Compile test data for evaluation
  - Positive and negative results



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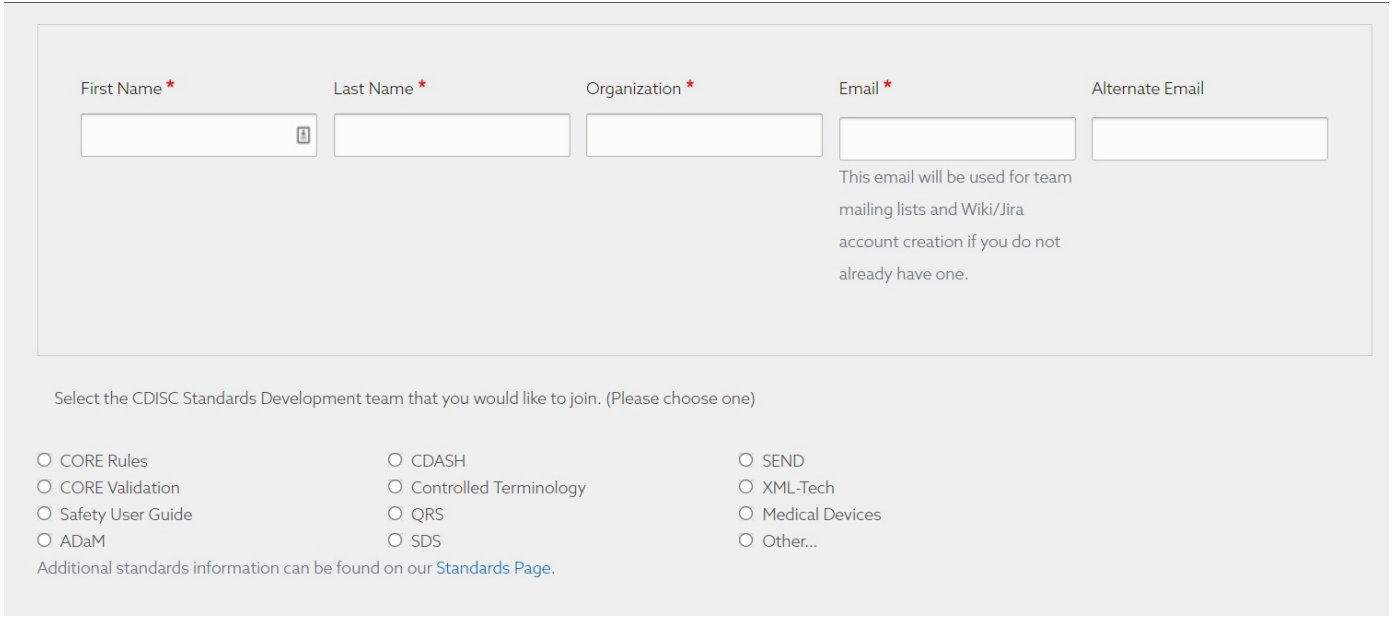
Validation Approach - SDLC

- An agile SDLC will be followed for the project
  - Define process (e.g., planning, sprints, hardening, testing, release, documents)
  - Incorporating validation into an agile SDLC
    - Validation deliverables
    - Define when artifacts are finalized and approved
    - Need for a hardening phase/sprint for formal testing of a release candidate
    - Define change control approach for future releases
- The process is currently in draft and will be used as a ‘dry run’ for the Minimum Viable Product (MVP)
- The process will be finalized prior to Release 1
  - Additional processes will be developed as needed

Sign Up



First Name *

Last Name *

Organization *

Email *

This email will be used for team mailing lists and Wiki/Jira account creation if you do not already have one.

Alternate Email

Select the CDISC Standards Development team that you would like to join. (Please choose one)

- CORE Rules
- CORE Validation
- Safety User Guide
- ADaM
- CDASH
- Controlled Terminology
- QRS
- SDS
- SEND
- XML-Tech
- Medical Devices
- Other...

Additional standards information can be found on our Standards Page.

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

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Thank You!

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