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**
Submit questions at any time – this webinar is an open forum
Audio issues?
Shut down & restart Zoom app
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)
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?
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**

- Design
- Develop
- Document & Publish
- Adopt
- Implement
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**

- Design → Develop → Document & Publish → Adopt → Implement → Automate

Automation requires:
- **Standard Machine-executable content for Useability**
- **Standard Technology Interfaces for Integration for Accessibility**
- **Standard Verification and Conformance Rules for Integrity**
### CDISC Standards in the Clinical Research Process

<table>
<thead>
<tr>
<th>PRE-CLINICAL</th>
<th>ORGANIZE</th>
<th>SEND</th>
<th>PLAN</th>
<th>COLLECT</th>
<th>ORGANIZE</th>
<th>ANALYZE</th>
<th>SUBMIT PUBLISH REPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DATA EXCHANGE</strong></td>
<td>PRM</td>
<td>CDASH</td>
<td>DATA EXCHANGE</td>
<td>SDTM</td>
<td>ADaM</td>
<td>DATA EXCHANGE</td>
<td>TAUGS</td>
</tr>
<tr>
<td>ODM-XML SDM-XML</td>
<td></td>
<td></td>
<td>ODM-XML</td>
<td></td>
<td></td>
<td>Define - XML Dataset - XML</td>
<td></td>
</tr>
</tbody>
</table>

**BRIDG, CONTROLLED TERMINOLOGY AND GLOSSARY**

![cdisc logo](https://example.com/cdisc-logo)
CDISC Standards

**FOUNDATIONAL STANDARDS**

<table>
<thead>
<tr>
<th>CDASH</th>
<th>SDTM</th>
<th>ADaM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard for data collection</td>
<td>Standard for structuring/formatting data</td>
<td>Standard for analysis datasets</td>
</tr>
<tr>
<td>Described in CDASH Implementation Guide</td>
<td>Described in SDTM Implementation Guide</td>
<td>Described in ADaM Implementation Guide</td>
</tr>
</tbody>
</table>

Demonstrate high-level implementation across broad use cases

Organized by domain/dataset

**THERAPEUTIC AREAS**

- Alzheimer's
- Diabetic Kidney Disease
- Malaria
- Asthma
- Schizophrenia
- Kidney Transplant
- Breast Cancer
- Ebola
- Pain
- Tuberculosis
- MS
- Diabetes
- Hepatitis C
- Prostate Cancer
- PKD
- CV Endpoints
- Influenza
- Dyslipidemia
- TBI
- Parkinson's
- Major Depressive Disorder
- COPD
- Rheumatoid Arthritis
- Virology

Demonstrate implementation of disease-specific use cases

Organized by biomedical concept

*The full list of foundational and therapeutic area standards are available at [https://www.cdisc.org/standards](https://www.cdisc.org/standards)*
CDISC Library

- Foundational Standards
- Controlled Terminology

Connect with Digital Data Processes through Open-API

CDISC Standards

- Biomedical Concepts
- Analysis Concepts
- Templates

Informative Content

- 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 Library

CDISC Standards

Informative Content
CDISC Library

Connect with Digital Data Processes through Open-API

Machine-executable content

Executable Conformance Rules

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
CORE Presentation
Conformance rules are an integral part of CDISC foundational standards and governed by community.

CDISC, CDISC Community and Health Authorities MUST govern the validation rules.

A single source of TRUTH which need to be Transparent, Open and Available (CDISC Library).

Conformance rules must be expressed in a common/layman language and should include executable component by governing community.

Need an “Open-Source” to community and endorsed by Health Authorities.

EXECUTIVE SUMMARY
**COMMUNITY NEEDS**
Golden Rules and one single TRUTH

**INDUSTRY VISION**
Integration with reporting environment

**HEALTH AUTHORITY NEEDS**
Data meets reviewer expectation

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

**WHY OPEN SOURCE?**
- Single source of TRUTH
- No ambiguity with specs vs Engine
- CDISC, Community and HA equally involved in full process
- Better data and review process
- No delay in process
- Integration with internal systems without any additional cost

- Bring more payers for better results
- Specs and Execution managed by same community
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
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](https://www.cdisc.org/core)
CORE Concept

COMMUNITY GOVERNANCE

CDISC Community

Executable

Specification

Conformance rules

Data Standards & rules

* 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
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

**Diagram Description**

- User interface for evaluation
- Engine for processing
- API for data standards and rules
- Test data and metadata loaded into the system
- Load data and rules for evaluation
- CDISC library for executable conformance rules
- CDISC-provided SaaS public cloud environment
- End user for evaluation

**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
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

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

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

CDISC

Vendor/User
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 System Architect
Software engineering team operational lead
Library team operational lead
Conformance Rules team operational lead
QA team operational lead

Scrum Master / Program Manager (Scrum of Scrums)
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

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>SDTM RG Version</th>
<th>Rule Version</th>
<th>Class</th>
<th>Domain</th>
<th>Variable</th>
<th>Rule</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>C00030</td>
<td>3.3</td>
<td>2</td>
<td>ALL</td>
<td>ALL</td>
<td>--TFF</td>
<td>--TFF and --TPN/NUM have a one-to-one relationship</td>
<td>VSN/NUM and --TPN/REF are not present in dataset</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Version, Business Version</th>
<th>Constraint, Scope</th>
<th>Constraint, Scope</th>
<th>Input</th>
<th>Pre-process Expression</th>
<th>Constraint, Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Needs disambiguation for shorthand &quot;ALL&quot;</td>
<td>Needs disambiguation for shorthand &quot;ALL&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 conditions exist in 1 statement.</td>
<td>Written for human.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
# Conformance Rules Development Team Roles

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards SMEs</td>
<td>Provide interpretation &amp; clarification from standards</td>
</tr>
<tr>
<td></td>
<td>Consult for rule development experience</td>
</tr>
<tr>
<td>Conformance Rule SMEs</td>
<td>Consult for cross-foundational harmonization effort</td>
</tr>
<tr>
<td></td>
<td>Consult for existing rule sets, such as disambiguation</td>
</tr>
<tr>
<td>Rule Developers</td>
<td>Create rules</td>
</tr>
<tr>
<td></td>
<td>Manage changes, e.g., versioning, corrections</td>
</tr>
<tr>
<td>Test Data Developers</td>
<td>Create and manage test data to evaluate rules</td>
</tr>
</tbody>
</table>
QA Team

**CORE QA team**

- Testing strategy
- Validation plan

**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
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
Questions & Answers
Audience Questions

What format will the reports be created in?
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?
Will the regulatory agencies adopt the CORE rules?
Audience Questions

How will CDISC work with vendors in this space?
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?
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
2021 CHINA INTERCHANGE
With Standards – Science Will Prevail!

Beijing | 6-7 August

2021 US INTERCHANGE
With Standards – Science Will Prevail!

Washington, DC, or Virtually | 18-22 October

Conference | Trade Show

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