CORE Status and Next Steps

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

COMMUNITY GOVERNANCE

CDISC Community

Executable Load

Specification Conformance rules

Data Standards & rules

End User

User Specific Rules

Configure and run

Data & Metadata

Interface

Engine

3rd Party application

API

CDISC Open-Source Alliance
CORE Program Roadmap

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

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

Q3 2021 – Q2 2022

Q3 2022 – Q2 2023

Q3 2023 – Q2 2024

Establish CORE Roadmap Board
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

![Diagram showing the planned deployment process]
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
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
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

CDISC Leadership
- Roles & Responsibilities
  - Establish CORE Roadmap & Technical Boards
  - Provide strategic guidance to Roadmap Board
  - Provide resources & staffing to CORE initiative
  - Determine open-source licensing approach

CORE Technical Board
- Roles & Responsibilities
  - Function as the Architecture Review Board
  - Approve architecture decisions
  - Determine the technology stack
  - Resolve development / technology related disputes
  - Develop testing strategy
  - Recruit other developers
  - IP and security assessments

CORE Roadmap Board
- Roles & Responsibilities
  - Promote CORE and drive adoption
  - Develop market requirements
  - Develop Roadmap
  - Approve release schedule
  - Facilitate Reference Implementation development
  - Develop and implement validation strategy
  - Engage community and foster collaboration
  - Ensure open/transparent/unbiased interaction with vendor community re commercial CORE development
  - Set strategic vision
  - Settle requirements & release planning disputes
  - Function as Product Owner

Most-Engaged Industry non-Technical Stakeholders
- Pharma-Biotech
- CRO
- Independent consultant
- Software vendor
- Regulatory agency

CDISC Standards Team
- Roles & Responsibilities
  - Develop conformance rules
  - Manage rules user feedback
  - Develop rules governance process
  - Apply rules versioning approach
  - Recruit & manage rules volunteer workforce

COSA
- Roles & Responsibilities
  - Framework for CDISC to actively support open-source apps
  - Manage which applications are published in COSA program
  - Provide guidance on open-source licenses
  - Collaborate with other clinical research open-source initiatives

Maintainer and Contributor Technical Community
- Pharma-Biotech
- Independent consultant
- Software vendor
- CDISC
- CRO

Requirements Working Group
- Gather market requirements

Testing Team
- Develop and implement testing approach

Validation Team
- Develop and implement validation approach

Developer Community
- Pharma-Biotech
- Independent consultant
- CDISC
- CRO
- Independent consultant
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**
  - SDTMIG v3.2 and v3.3 Rules

- **Complete Q1 2023**
  - SENDIG Rules

- **Complete Q2 2023**
  - ADaMIG Rules

- **Complete Q3 2023**
  - ADaMIG Rules

- **Begin Q1 2023**
**CORE Engine Planning**

### MVP Initial Development
- **CORE Engine**
  - CORE Engine v202204

### MVP Evaluation Phase
- **CORE Engine Build X**
- **CORE Engine Build X+1**

### Production Reference Implementation
- **CORE Engine Build X+2**

### CORE Deployment
- **CDISC-provided public cloud deployment**
  - Now Apr 2022
- **Planned private cloud deployment**
  - Estimated Jun 2022
- **Planned on-premises deployment**
  - Estimated Dec 2022
- **CDISC Production Release**
  - Estimated Jun 2023

### Commercial Release
- **Commercial Release Development**
- **Commercial Production Releases**

- **Launch April 2022**
- **Publish in GitHub**
  - Release as Open Source
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
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 end of May
- Planning rules development workshops
  - CDISC US Interchange
  - PHUSE EU Connect

*Wanted: ADaM, SDTM, and SEND Volunteers!*
Thank You!