WITH STANDARDS - UNLOCK THE POWER OF DATA



2022 EUROPE INTERCHANGE 27-28 APRIL | VIRTUAL EVENT



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

cdisc



* CDISC Open-Source Alliance



CORE Overview

CORE Program Roadmap





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



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

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CORE UI Dashboard

CDISC Open Rules Engine

Welcome Peter Van Reusel 🝳

⋒ ₽	Conformance Validator	Welcome to CDISC CORE							
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		CDISCPILOT01	Issues	SDTM	2022-04-01T12:54:34		Product Inquiry Form Service Deck		
		CDISC-TEST	Original	SDTM	2022-04-01T11:40:52		> Release Notes		
		MarisaTEST01	issues	SDTM	2022-03-29T14:12:00	-	> How-to Articles		
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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



CORE Engine Planning

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!

