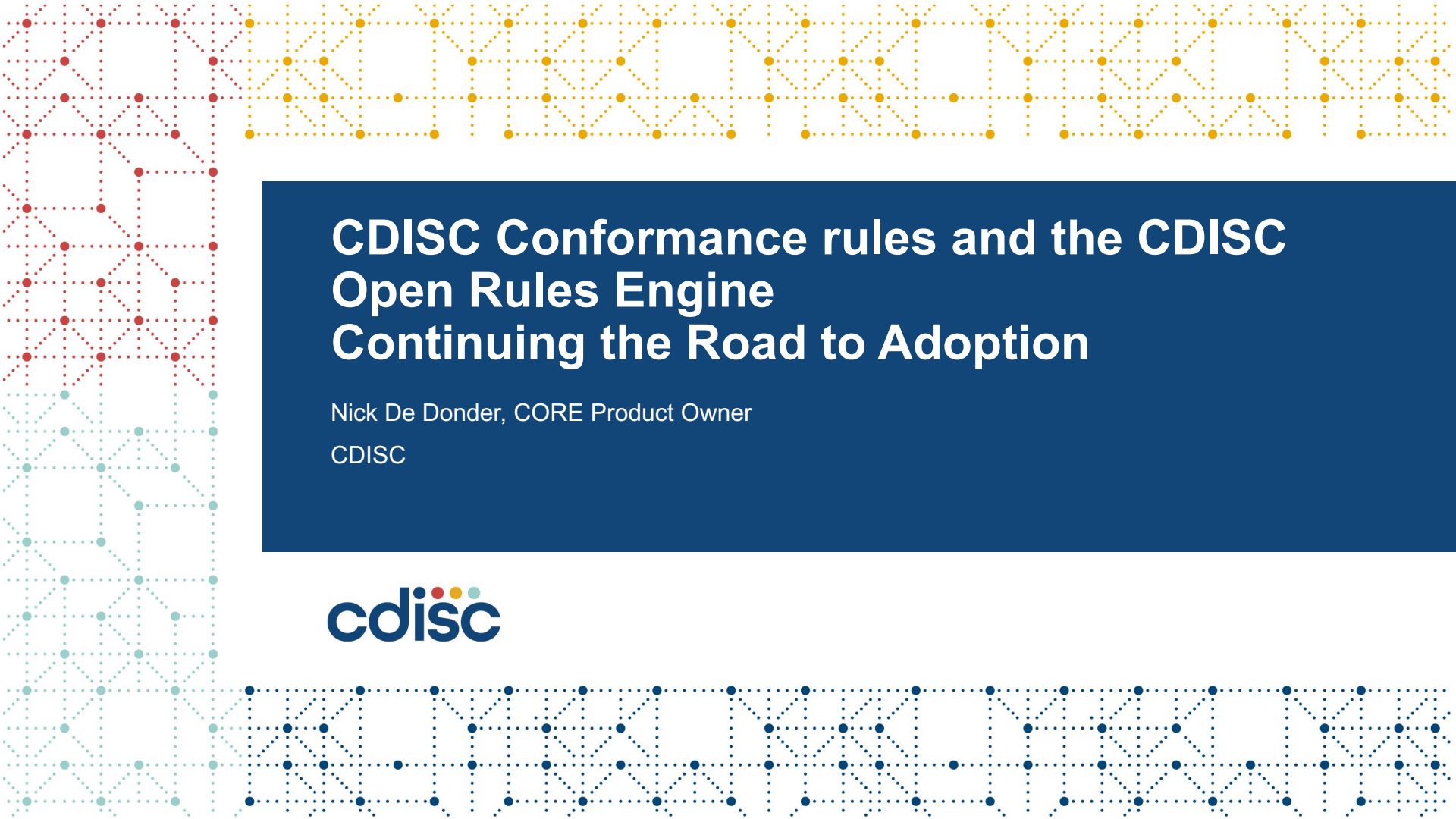




CDISC Conformance rules and the CDISC Open Rules Engine Continuing the Road to Adoption

Nick De Donder, CORE Product Owner

CDISC





Agenda

- CORE Concept
- Conformance Rules
- Rules Governance Model
- CORE Engine and Deployments
- What's Next



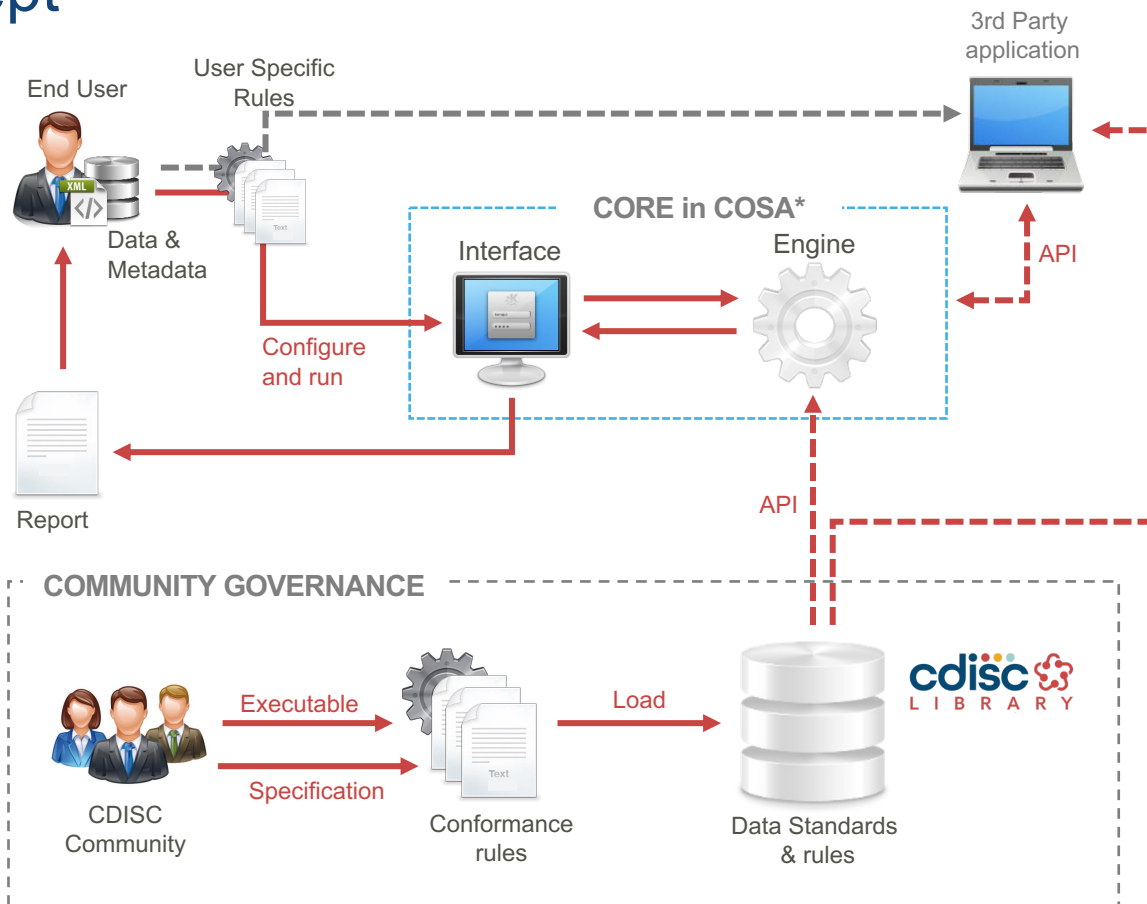
CORE Concept

The Challenge

A single source of truth for all conformance rules

Consistency across conformance rule implementations

CORE Concept



* CDISC Open-Source Alliance



Conformance Rules

```

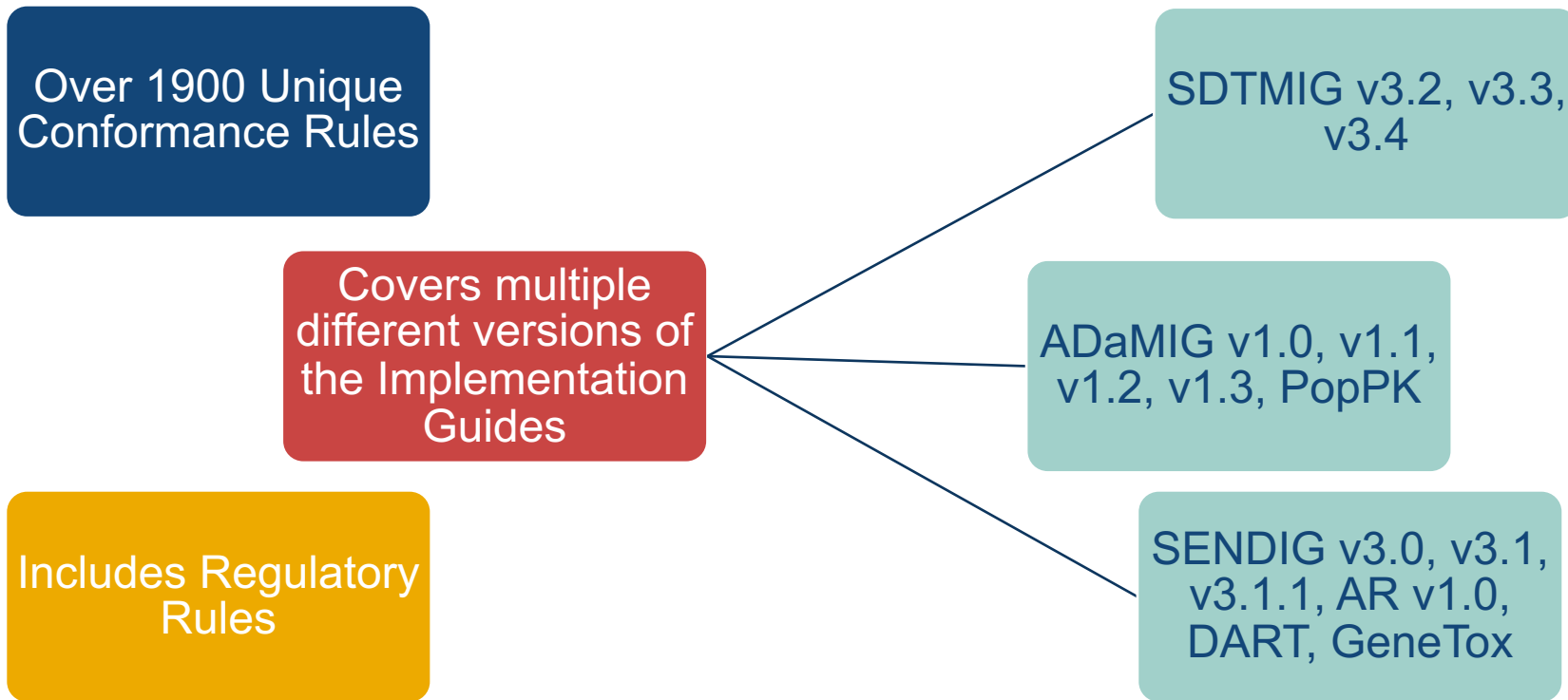
1  # Variable: EXMETHOD
2  # Condition:
3  # Rule: EXMETHOD not present in dataset
4  Authorities:
5    - Organization: CDISC
6      Standards:
7        - Name: SDTMIG
8          References:
9            - Citations:
10              - Cited Guidance: Method of administration of the treatment. Not to be used with
11                human clinical trials.
12                Document: Model v1.7
13                Item: EXMETHOD
14                Section: Table 2.2.12.1
15                Origin: SDTM and SDTMIG Conformance Rules
16                Rule Identifier:
17                  Id: CG0568
18                  Version: '1'
19                  Version: '2.0'
20                  Version: '3.3'
21  Check:
22    all:
23      - name: EXMETHOD
24        operator: exists
25  Core:
26    Id: CORE-000326
27    Status: Published
28    Version: '1'
29    Description: Trigger error when EXMETHOD exists in the EX dataset for human clinical trials
30    Executability: Fully Executable
31    Outcome:
32      Message: EXMETHOD is not to be used with human clinical trials
33    Rule Type: Record Data
34    Scope:
35      Classes:
36        Include:
37          - INTERVENTIONS
38      Domains:
39        Include:
40          - EX
41    Sensitivity: Record
42

```

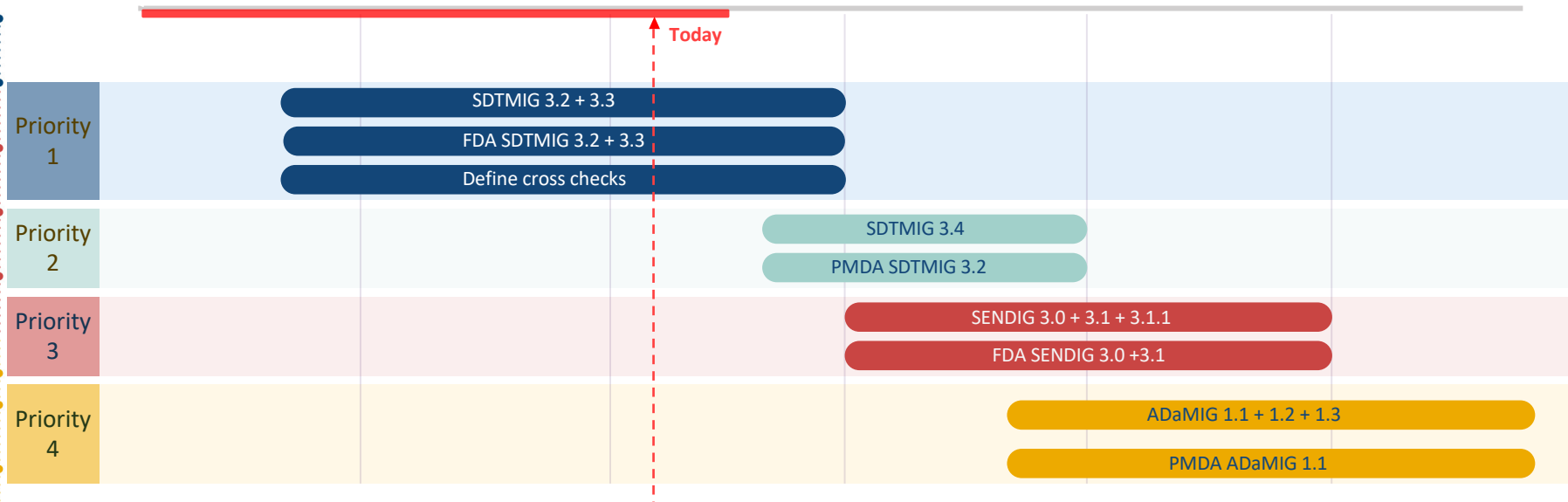
CORE Rule Editor

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

Volume and Breadth of Conformance Rules

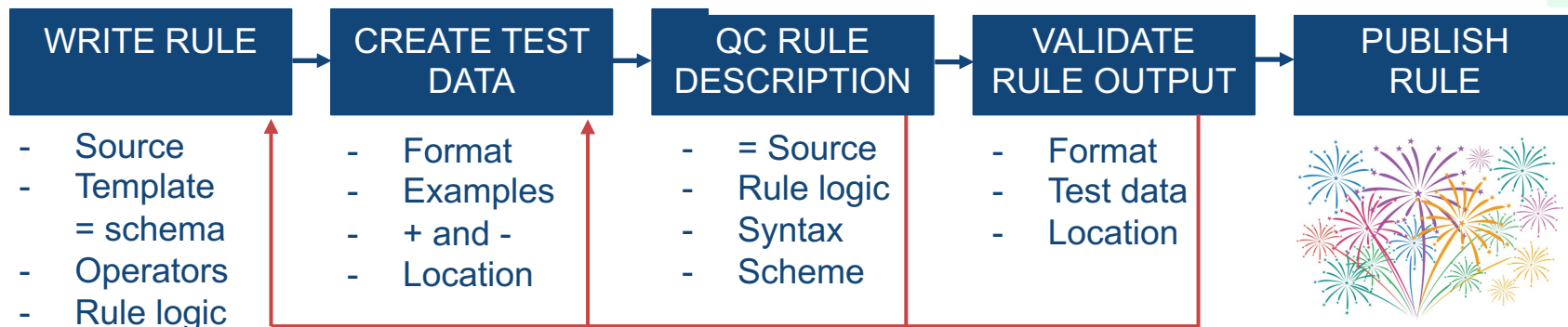
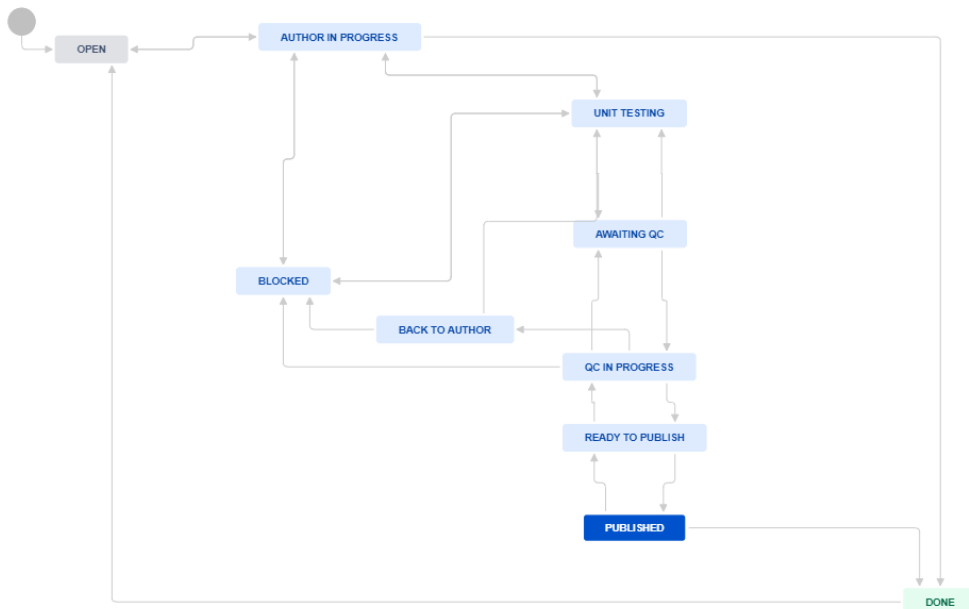


Rules Development Priority



➡ *Timelines depend on community engagement*

Rules process



Developing CORE Rules in the Future



Plan to draft the rule logic within the CORE Rules Editor



Use the Rule Description and Outcome Message to review rule during Internal and Public Review



Cited Guidance is part of the Rule



Rule Logic is transparent



Rules Governance Model

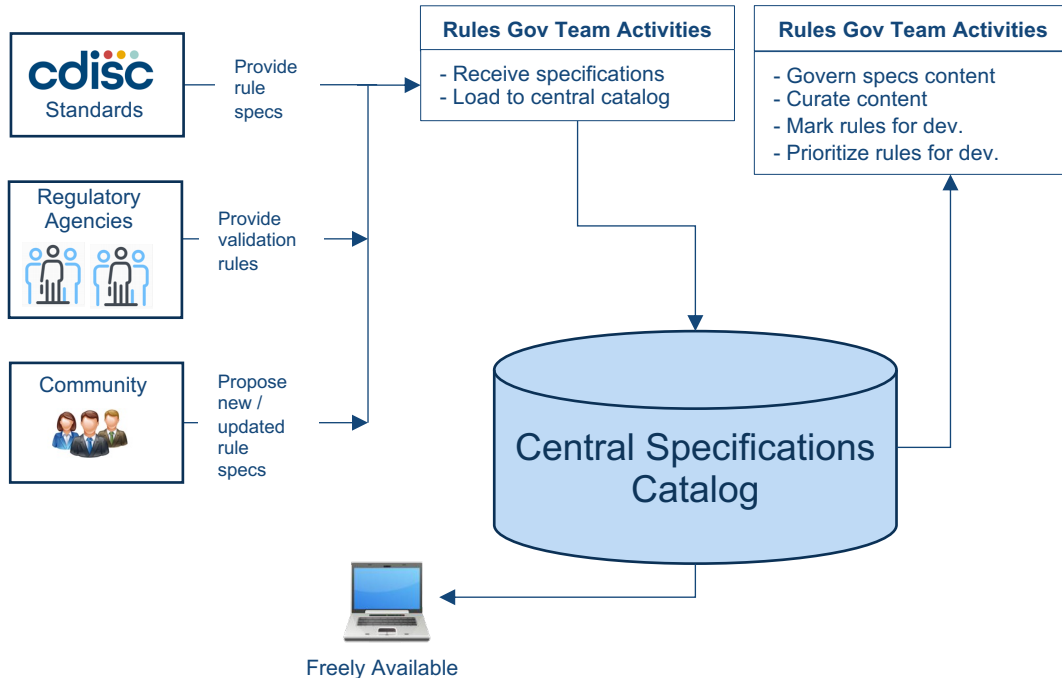
CORE Rules Governance



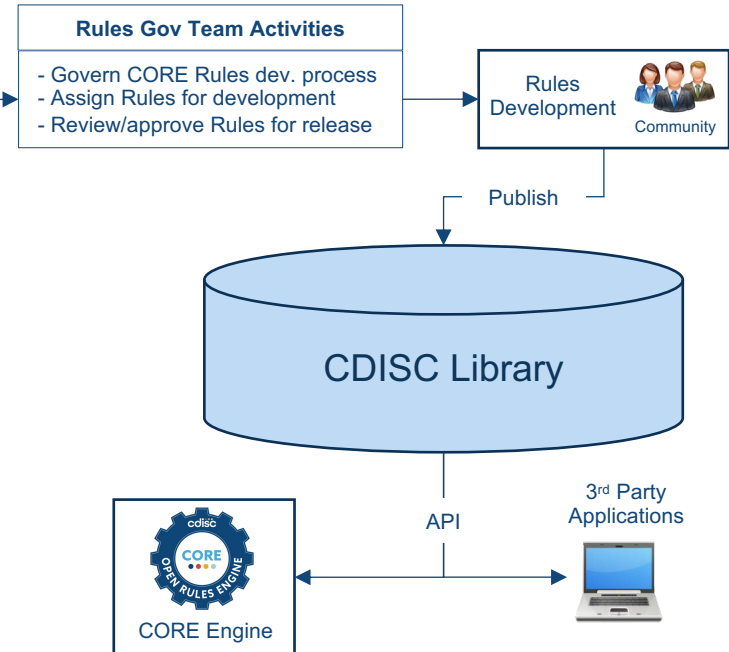
Rules Governance Team

(CDISC; Regulatory Agencies; Community)

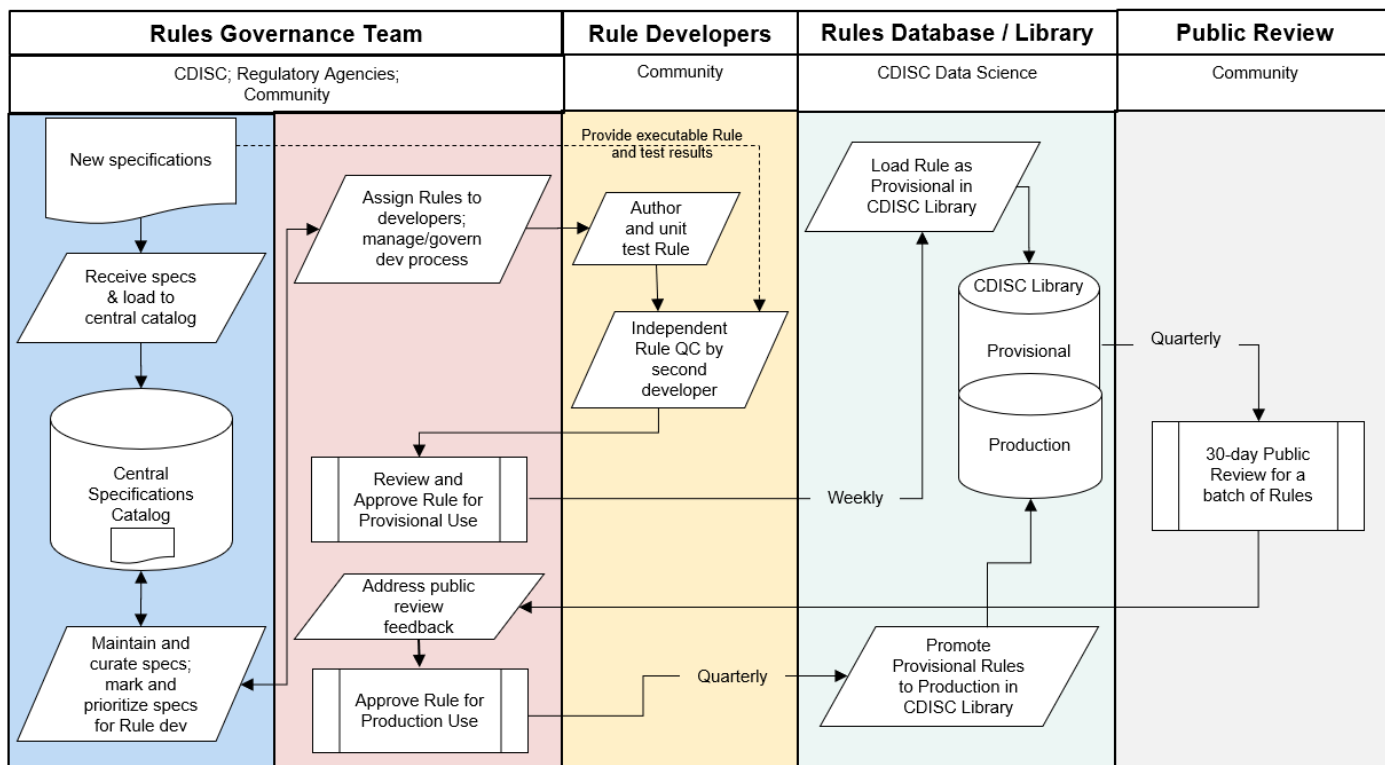
Rule Specifications



CORE Rules (executable)



Conformance Rules: Governed Development Process



➡ *Governance model is complete; implementation is in progress*



CORE Engine and Deployments

CORE Software: Engine and Rule Editor

- Each project
 - Has a public GitHub repository on the cdisc-org account and is listed on the COSA Directory
 - Has been released under the MIT open-source license
 - Development is led by CDISC
 - Still under development, but are being actively used
 - Can be extended (supports the development of software extensions)
- CORE Engine
 - Written in Python
 - Makes use of the Venmo Business Rule Engine
- CORE Rule Editor
 - Written in TypeScript
 - Makes use of the VSCode editor



Running the CORE Engine

- Source Code
 - Available on GitHub using the MIT open-source license
- CLI executable available in GitHub
 - Cached rules
 - Windows, Mac, and Linux install packages
 - Unzip and run
 - Will need datasets to validate
- Engine available on PyPI
 - Engine is a component that can be used in your own code
- Desktop versions
 - Vendor released versions of CORE
 - Includes a user-friendly UI
 - Easier for non-technical users to evaluate
- View a short CORE demonstration
 - <https://www.cdisc.org/core>
 - See **CORE on GitHub** tab



Third-party Desktop Deployments

- Early discussions with vendor community re early provision of standalone CORE Engine desktop version
 - Simple to install and use
 - Provide a UI
 - Will make it easier for the CDISC community to evaluate CORE without IT support
- First free, publicly available, vendor-provided CORE desktop version announced at the CDISC European Interchange
- CORE is a Reference Implementation
 - The principle is commonly used in the software industry
 - Provides a concrete example on how the standard should be implemented

 *Drive adoption*



CORE Registered Solution Provider

- Program purpose
 - For CORE vendors (solution providers)
 - Certify with CDISC that their solutions correctly use the Conformance Rules
 - For CDISC
 - Treat all CORE vendors equally
 - Achieve a level playing field regarding use of any Engine with the Conformance Rules
 - Inform the community which solutions have been certified
- Testing for certification will include
 - Generating results with Conformance Rules and test study data reflecting an “average study”
 - No system functionality testing



What's Next

Adoption by Regulatory Agencies

- One version of the truth will benefit the regulatory submission ecosystem
- CDISC and FDA are discussing joint governance and publication of rule specifications
- Single version of rule specifications followed by single version of executable rules implementation

 *A future where regulatory agencies use CORE Rules*

Adoption by Industry

- TransCelerate Digital Data Flow
 - Conformance Rule Proof of Concept on Unified Study Definition Model (USDM)
- Tobacco Implementation Guide
 - Creating new TIG-specific rules
 - Aligning with existing conformance rules
- Various Implementations with Vendors, Sponsors, and CROs

 *Moving forward with additional implementations*



Next Milestone

- The complete ruleset for
 - SDTM 3.2 and SDTM 3.3
 - Define.xml crosscheck rules
 - FDA business rules v1.5 (that apply to SDTM 3.2 and SDTM 3.3)
 - FDA Technical Rejection Criteria
- CORE Engine Stable Release
 - Engine can run all the rulesets above
 - Thorough testing and validation documentation
- Purpose
 - Test with real study data and roll out rules governance process



*Implementers can integrate this stable version
Drive adoption and test with real study data*



In Summary

- Rules
 - Full set of executable rules for submission standards (SDTM, SDTMIG, SENDIG, ADaMIG)
 - Including Regulatory-specific rules
 - Including Define.xml cross-check rules
 - ➔ *Continuing volunteer engagement is critical!*
- CORE is the Reference Engine
 - Engine with all basic functionality for full set of machine-executable rules
 - Includes a validation package
- CDISC will establish a CORE certification program
 - To verify output of different applications versus the CORE Reference Engine
 - CDISC conformance rules are the single version of the truth



*Rules are part of the Standards!
Expect Regulatory Agencies to mandate use of CDISC Conformance Rules*



Thank You!

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