2026 Korea CDISC Day

29 October 2026 · Seoul, Korea

# CDISC Open Rules: Progress, Performance, and Foundations for the Future

Tomás Sabat Stöfsel, CEO & Co-Founder, Verisian

29 October 2026



# Agenda

1. Why CDISC Open Rules Matter
2. CDISC Open Rules v1.0 – Progress So Far
3. Engine Refactor
4. Verisian platform integration
5. Improved Rule Authoring Process

# Speaker



Tomás Sabat Stöfsel

CEO & Co-Founder

Verisian

# Why CDISC Open Rules Matter

… and why they matter to you …

# CDISC Conformance Rules and Regulatory Requirements

## TODAY

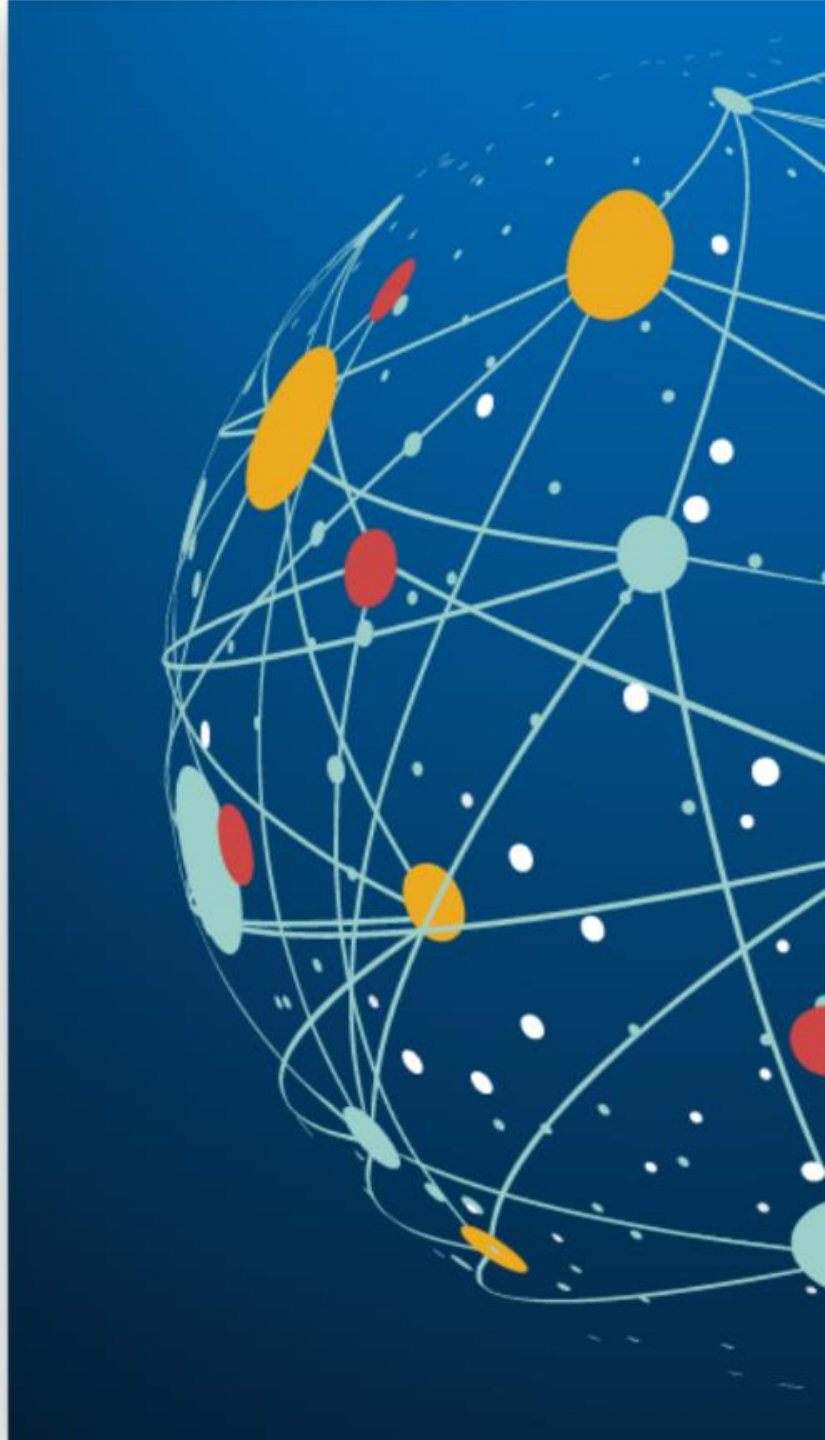
- Various source formats and structures
- Specifications that are not machine-executable
- Variety in interpretations of rule purpose
- Individual implementations to executable code

**Lack of consistency in data for regulatory submissions**

## GOAL

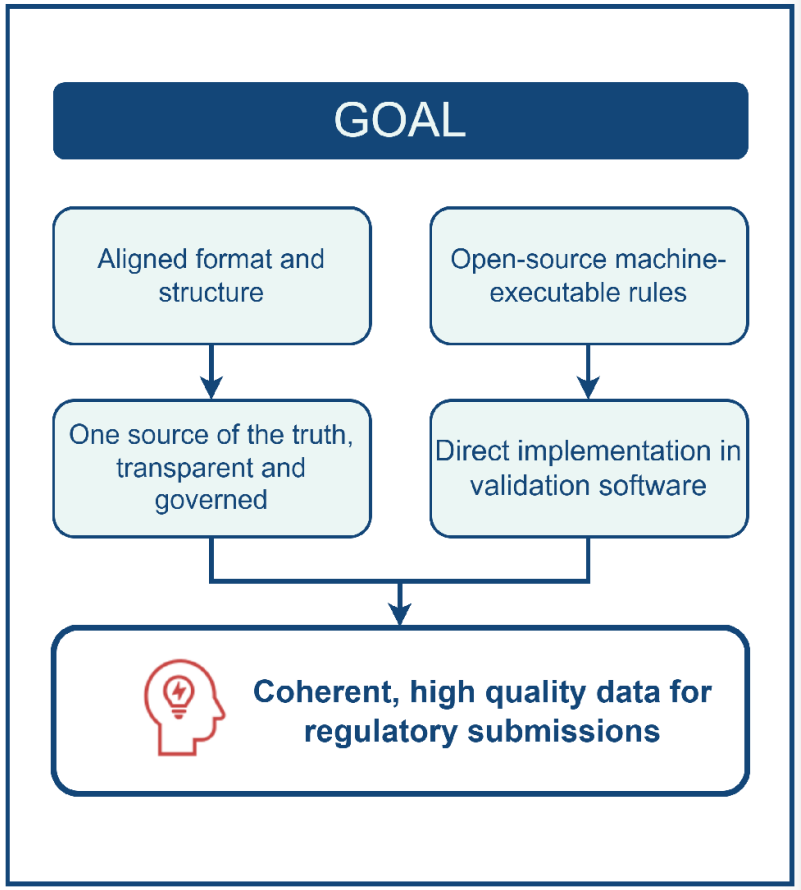
- Aligned format and structure
- Open-source machine-executable rules
- One source of the truth, transparent and governed
- Direct implementation in validation software

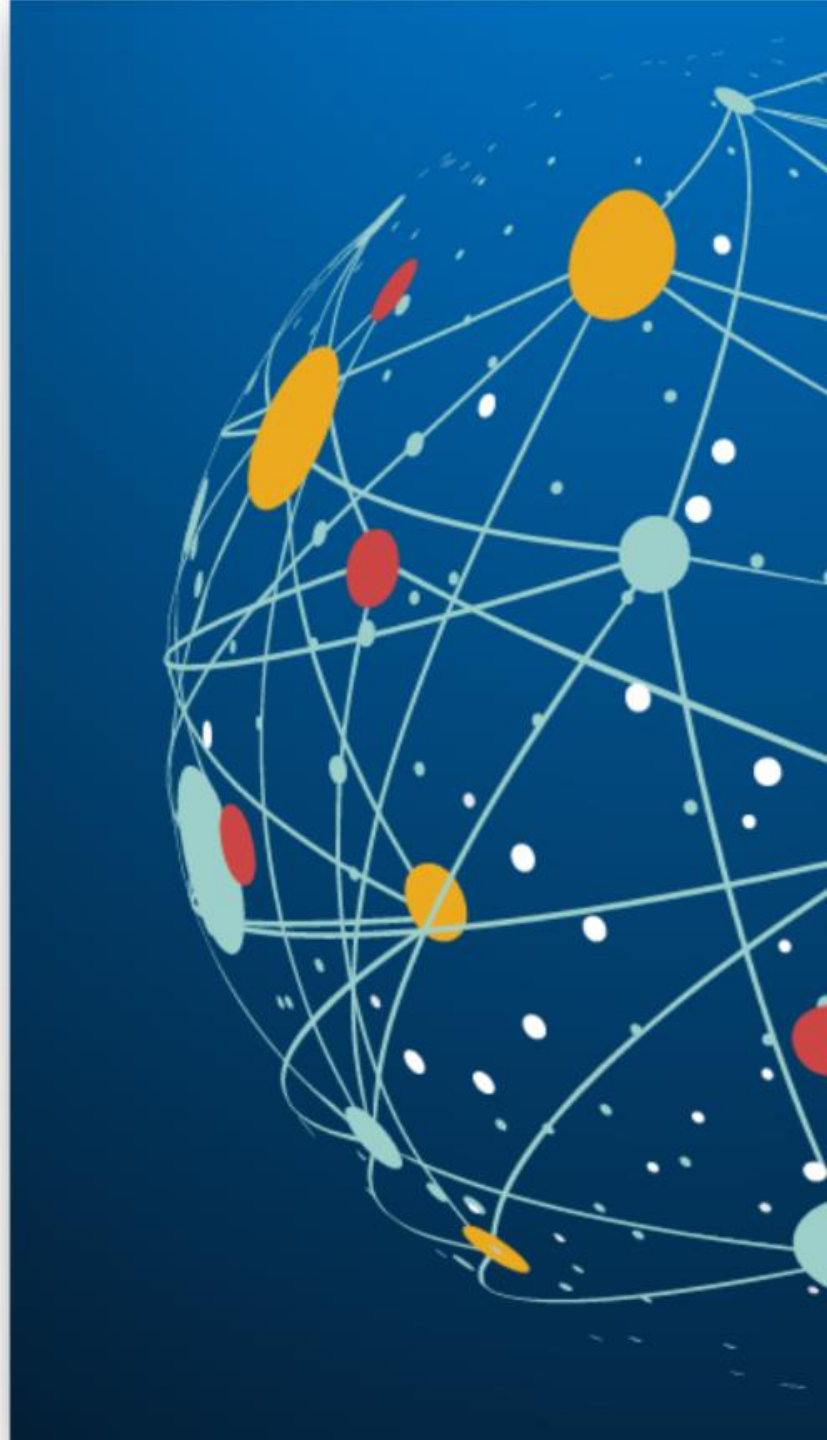
**Coherent, high quality data for regulatory submissions**



# CDISC Conformance Rules and Regulatory Requirements



# Rule Authoring Status for v1.0

| Standard | # Rules | % Written | % Verified |
|---|---|---|---|
| SDTMIG v3.2, 3.3, and 3.4 | 473 | 100% | 98% |
| FDA Business Rules (SDTMIG) | 186 | 100% | 98% |

# Rule Authoring Status for ADaMIG

| Standard | # Rules | % Written |
|---|---|---|
| ADaMIG v1.0, 1.1, 1.2 and 1.3 | 802 | 79% |

- *Started authoring ADaM rules. These completed rules are unverified but CDISC verification will start shortly after SDTMIG completion and v1.0 release*

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79% written in 2 weeks!

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*With pgserver the engine runs locally without any performance drop

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| | |
| | |
| | |
| | |

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The refactored engine removes dataset size and scalability limitations while improving accuracy and error reporting

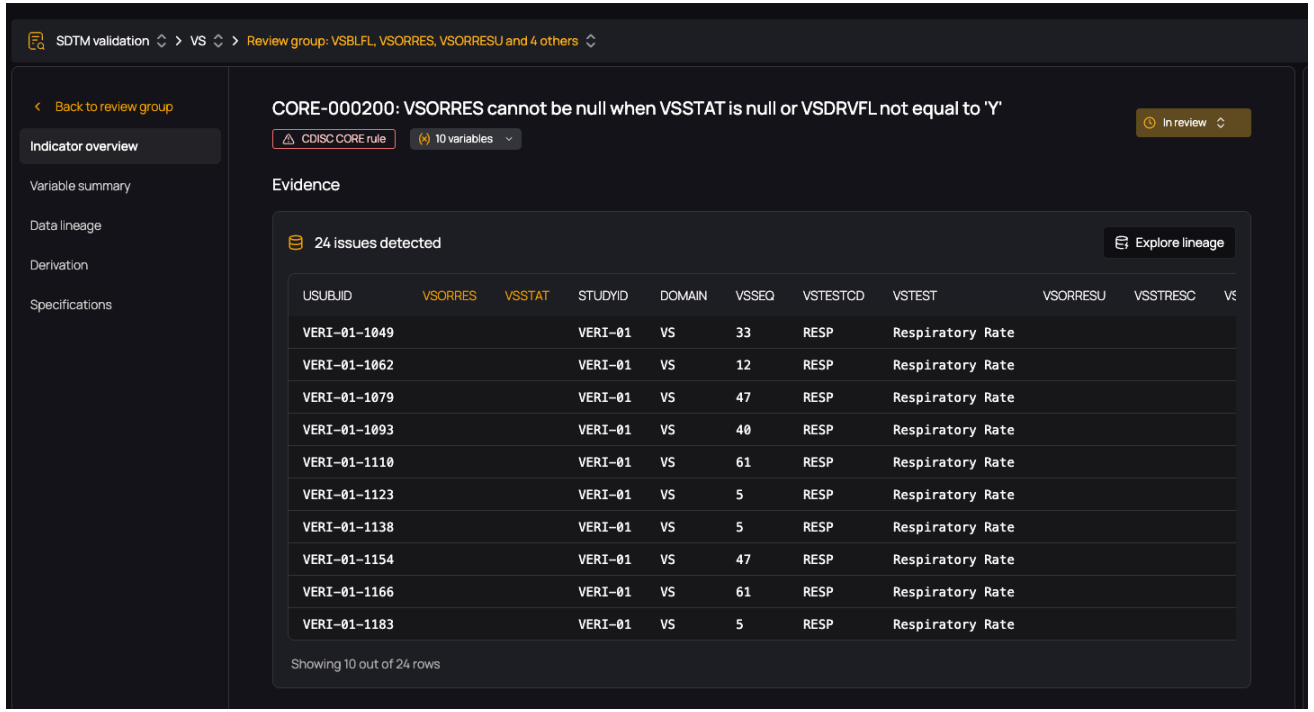
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# Further development to the Engine is on the way…

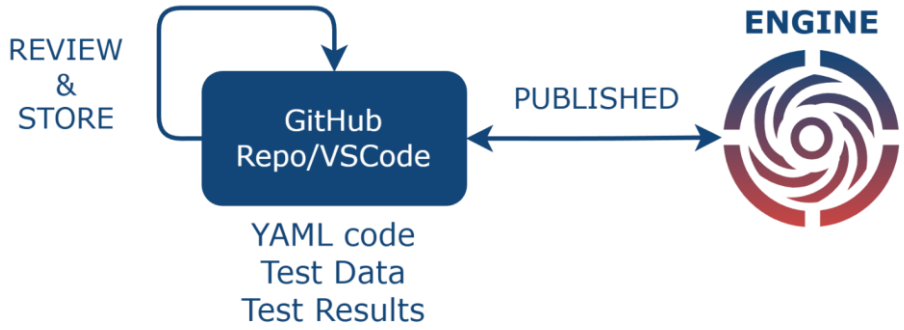
- Faster data ingestion
- Logic for execution of several large previously non-executable rules
- Up to 12x faster validation run-time

# Verisian Platform Integration

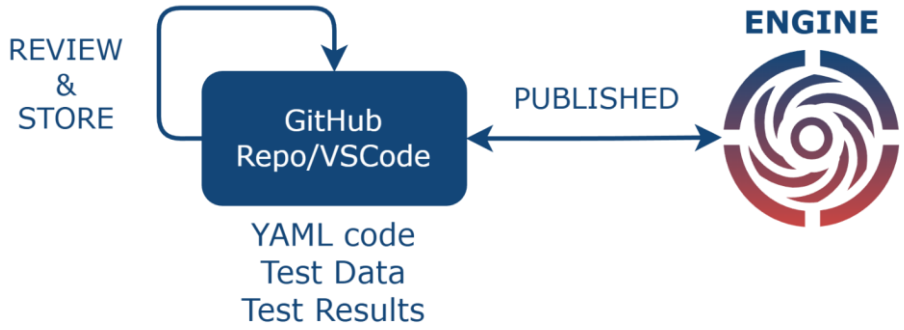
- Full integration with the Verisian suite:
  - See all your issues and only your issues
  - Browse issue by variable and dataset
  - Downloadable excel report
  - Links to rest of data validation suite tools



# Improved Rule Authoring Process



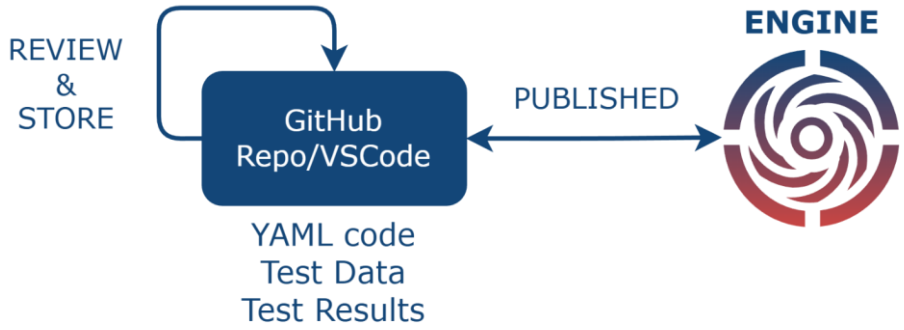
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## Centralized and Trackable Workflow

- Git-based rule repository for storing, versioning, and tracking
- Streamlit dashboard for quick analysis and progress visibility

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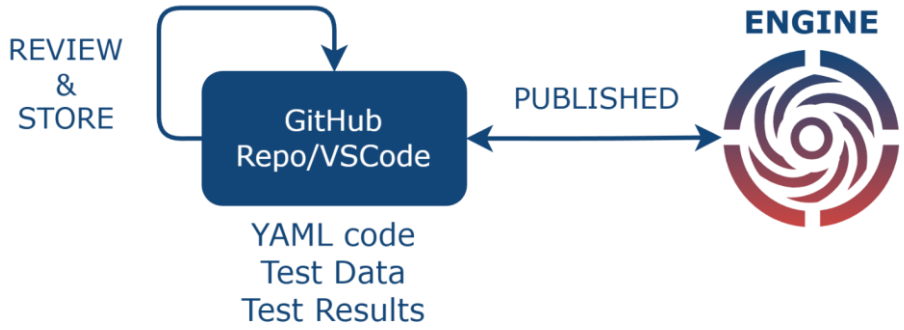

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## Easy and Guided Contribution

- Simple setup scripts and clear contributor guide
- Accessible to all skill levels
- Structured review process

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## Integrated Training and Testing

- Built-in training materials
- Automated testing within the repository

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- Rule-creation scripts:
  - Allows contributors to focus solely on writing rule logic
  - Eliminates human error

# Thank You!



# Questions?

tomas@verisian.com

