CDISC Open Rules / CORE v1.0 Release Public Webinar

Julie Smiley | CDISC
Els Janssens | SGS
Richard Stone | Verisian
Dianna DiRusso | CDISC

10-November-2026



1. Why Open Rules: the problem we set out to solve
2. Open Rules packages
3. CORE V1.0 overview
4. What remains and how to get involved in completing remaining rule packages
5. The future machine-readable rule model: what it means and how to participate
6. Community Q&A

Housekeeping

- Audience will be on mute during this session.

Shhhh…

- Please submit via Q&A in the Teams App.

Questions?

- First, restart Teams.
- Second, check your local internet connection strength

Audio Issues?

- A recording of this webinar and slides will be available on Public Webinar Archive on CDISC website.

Recording

Why Open Rules

The problem we set out to solve

The problem we set out to solve

Conformance rules have always been part of the standards, but they were written for people, not machines

Open to interpretation

Each organization read and interpreted the conformance rules its own way, which led to different implementations of the same rule within tooling

Inconsistent results

The same study could get different findings depending on which implementation was run

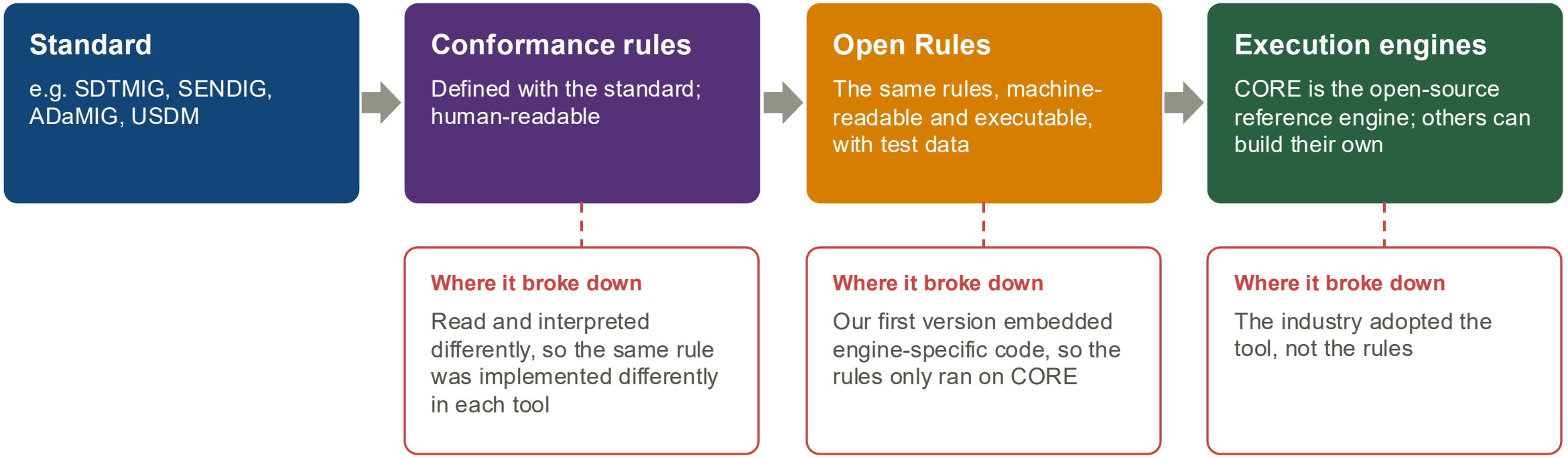
Logic hidden inside tools

No one outside the tool could see exactly what was checked, or why

Open Rules turn written guidance (conformance rules and FDA Business rules) into transparent, machine-executable rules that reduce ambiguity and that anyone can inspect.

What we learned: Open Rules are a machine-readable standard

How a conformance rule becomes something a machine can run, and where it broke down



What we learned: Open Rules are a machine-readable standard in their own right. CDISC develops and governs them, every rule ships with test data and evidence, and CORE is one engine that runs them.

Open Rules Packages

CORE v1.0: What Rule Packages Are Included?

1. CDISC Conformance Rules based on the SDTM Models and IGs

SDTM and SDTMIG Conformance Rules			
IG version	**Number of conformance rules**	**Number of conformance rules that are not executable**	**Number of CDISC Open Rules**
SDTMIG v3.2	411	47	377
SDTMIG v3.3	449	53	411
SDTMIG v3.4	455	63	411

Not executable: Rules that cannot be automated because they depend on information or interpretation not available to the rule engine.

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CORE v1.0: What Rule Packages Are Included?

2. FDA Business Rules for Clinical Study Data

FDA Business Rules v1.5			
IG version	**Number of conformance rules**	**Number of conformance rules that are not executable**	**Number of CDISC Open Rules**
SDTMIG v3.2	183	5	173
SDTMIG v3.3	185	5	177
SDTMIG v3.4	188	5	180

FDA Business Rules: 43 rules → 180+ conformance rules → ~180 Open Rules per IG

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621 unique Open Rules



Why totals don’t simply add up

- Overlapping CDISC & FDA rules combined
- Multiple IGs covered by a single Open Rule
- Multiple source rules may become one Open Rule
- One source rule may result in multiple Open Rules

From Published Requirements to Open Rules



YAML rule definition

- Rule translated into executable logic
- Flags data that violates the rule
- Read and executed by the validation engine

From Published Requirements to Open Rules

Each rule required

- Examination and clear interpretation
- Defined applicability and documented decisions
- Unambiguous, executable logic
- Standardized output
- Positive and negative test data
- Testing, review, and approval

A complete Open Rule combines the requirement, logic, output, and test evidence

Behind an Open Rule: A Practical Example

Example: CG0175

```
Condition: IECAT = 'EXCLUSION'
     Rule: IEORRES = 'Y'
```

Rule metadata: identifiers, standard, cited guidance

```yaml
Authorities:
  - Organization: CDISC
    Standards:
      - Name: SDTMIG
        References:
          - Citations:
              - Cited Guidance: The intent of the domain model is to collect responses to only
                  those criteria that the subject did not meet, and not the
                  responses to all criteria.
                Document: IG v3.4
                Item: Assumption 1
                Section: 6.3.4
            Origin: SDTM and SDTMIG Conformance Rules
            Rule Identifier:
              Id: CG0175
              Version: '1'
            Version: '2.0'
        Version: '3.4'
```

Rule logic: scope, condition, rule

```yaml
Check:
  all:
    - name: IECAT
      operator: equal_to
      value: EXCLUSION
      value_is_literal: true
    - name: IEORRES
      operator: not_equal_to
      value: Y
      value_is_literal: true
Core:
  Id: CORE-000011
  Status: Published
  Version: '1'
Description: Raise an error when IECAT is equal to 'EXCLUSION' and IEORRES is
  not equal to 'Y'.
Executability: Fully Executable
Outcome:
  Message: IEORRES is not equal to 'Y', but IECAT is equal to 'EXCLUSION'.
  Output Variables:
    - IETESTCD
    - IECAT
    - IEORRES
Rule Type: Record Data
Scope:
  Classes:
    Include:
      - FINDINGS
  Domains:
    Include:
      - IE
  Use Case: INDH
Sensitivity: Record
```

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```

CORE-ID used by the engine and shown in the issue report.

Where Can You Find the Released Rule Packages?

- YAML rule definitions are included in the CORE v1.0 release
- The Open Rule packages can also be explored via the CDISC Library API : https://api.developer.library.cdisc.org/api-details
- Complete rule folders with YAML code, test data and evidence: https://github.com/verisianHQ/core-contributor/tree/main/sdtm_rules

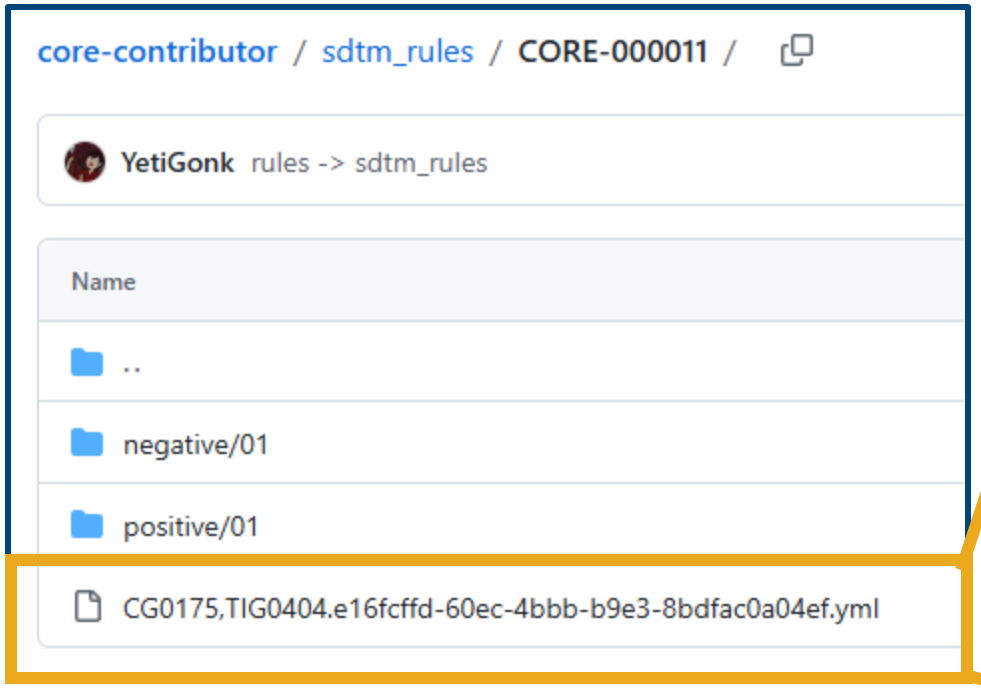


Rule + test data + evidence in one place = built-in traceability, reproducibility, and trust

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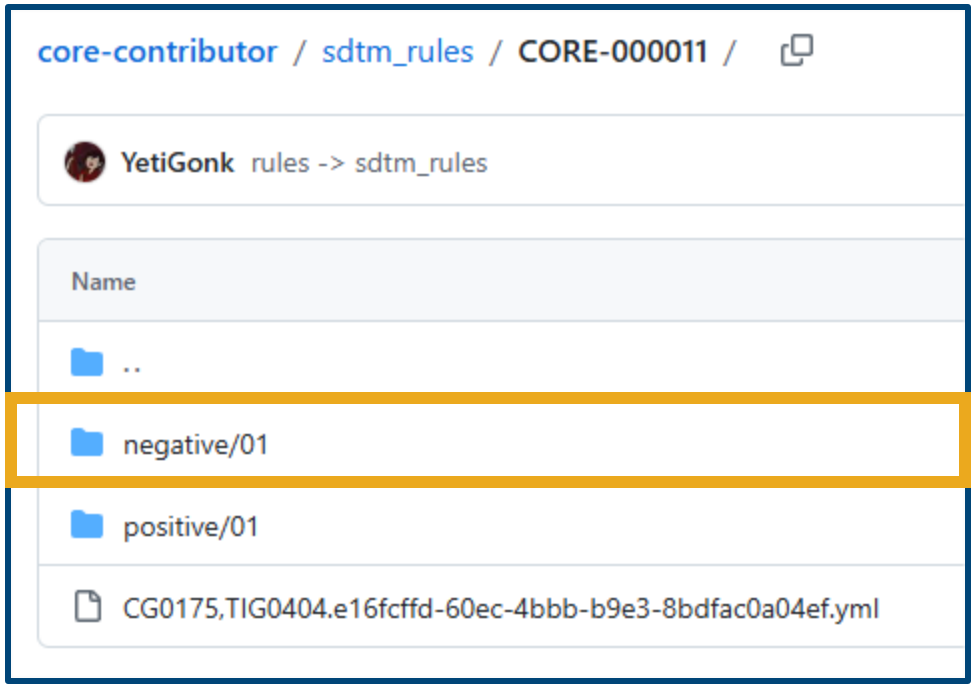


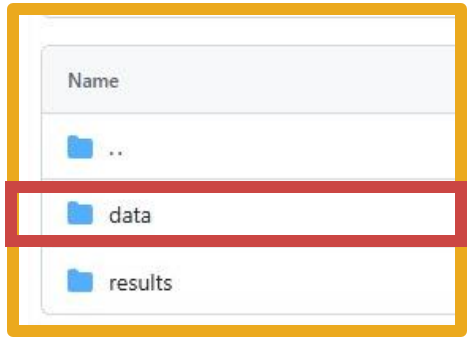


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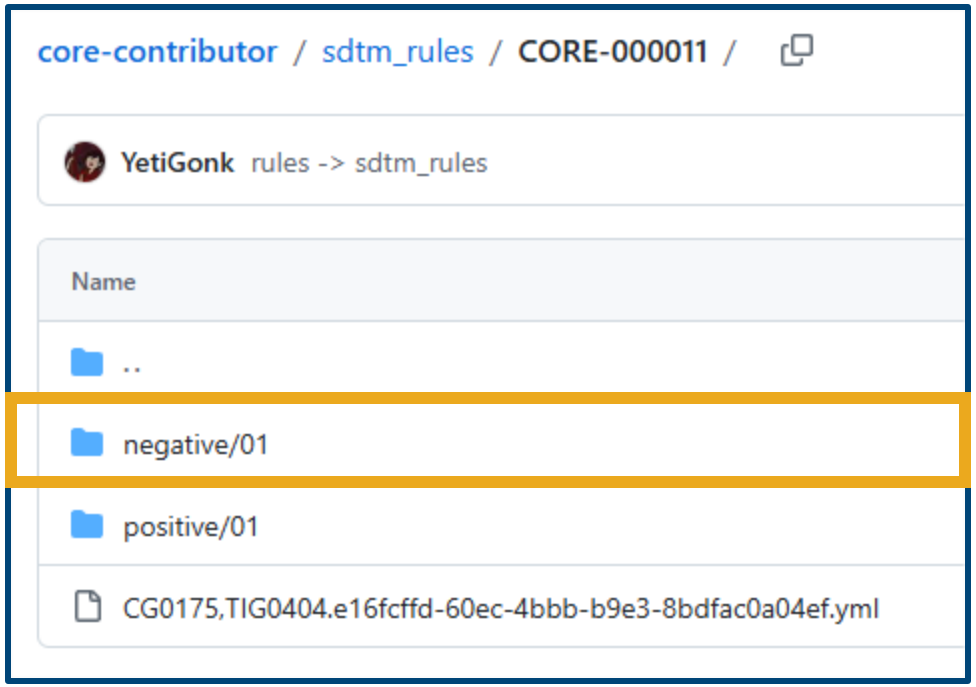


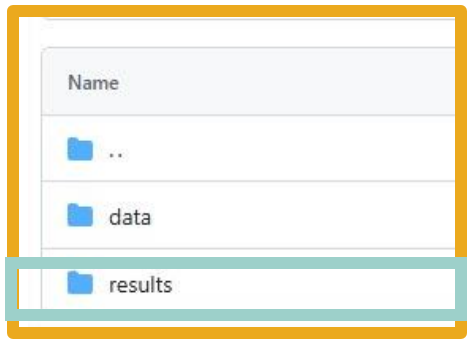


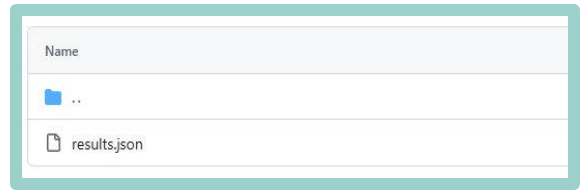
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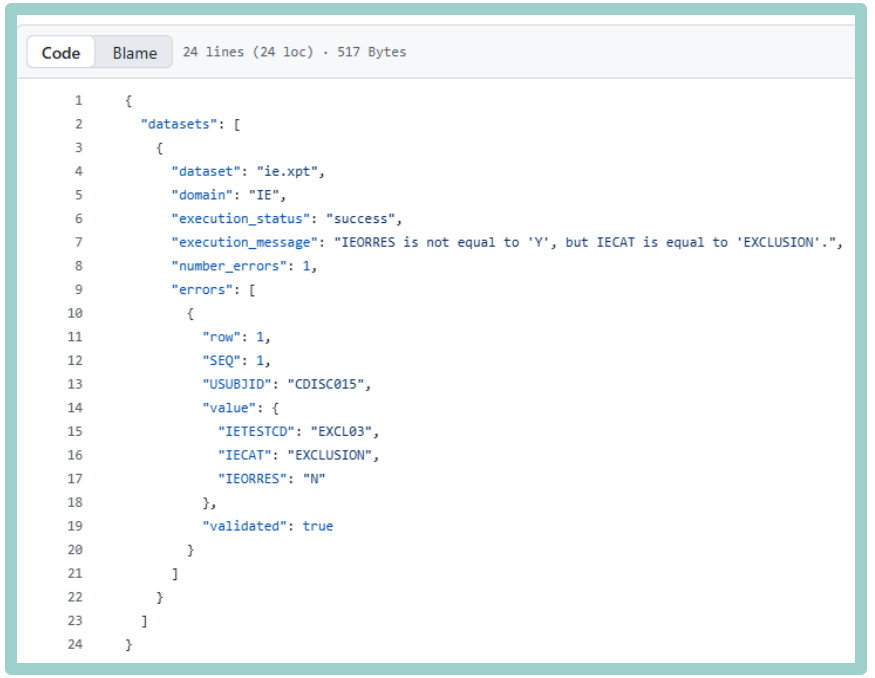
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Connecting Open Rules to Their Source

Rule Mapping Document: core-contributor/docs/rule_mapping.md at main · verisianHQ/core-contributor

- Overview of which Open Rule, identified by its CORE-ID, maps to each source conformance rule
- Implementation notes

CDISC Open Rules Engine (CORE) v1.0 Overview

Open-source reference implementation

What is CORE?

The rules say what to check. The engine checks the data. The report shows what was found.

1 Open Rules

Machine-readable SDTM and FDA rules, published by CDISC

2 CORE engine

Open-source software that runs every rule against your study datasets

3 Report

An Excel report listing every issue, and the run status of every rule

How you run it: type one short command in a terminal window (the “command line”)

- No programming needed
- Your data never leaves your machine

What's in CORE v1.0

621

unique Open Rules, all ready to run

SDTMIG 3.2 · 3.3 · 3.4

Included

- All **SDTM and SDTMIG Conformance Rules v2.0**
- All **FDA Business Rules v1.5**
- Rules that use your define.xml
- Your own custom rules and custom standards

Not in v1.0 yet

- ADaM rules and Define-XML rules: in development
- Dataset-JSON input: CORE reads XPT and SAS7BDAT

A new engine: from pandas to PostgreSQL

Previous engine (pandas)	CORE v1.0 (PostgreSQL)
• Loads every dataset fully into memory • Each rule re-processes the data in Python • Memory and run time grow quickly with study size	• Loads the data once into a database • Each rule is an optimised query, using indexes • New operators and operations

Why it matters: the database does the heavy lifting, so far bigger studies run faster on the same laptop.

Try it yourself: four steps

1

Download

Needs Python 3.12. Get the v1.0.0 release

```
git clone --branch v1.0.0 \
  https://github.com/verisianHQ/cdisc-rules-engine
```

2

Install

A private Python environment, then the requirements

```
python3.12 -m venv venv
source ./venv/bin/activate
python -m pip install -r requirements.txt
```

3

Validate

Rules and database included: nothing else to set up

```
python core.py validate -s sdtmig -v 3-4 \
    -d path/to/datasets
```

4

Read the report

Excel, in the folder you ran the command from

```
CORE-Report-<date and time>.xlsx
```

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Options worth knowing

Database

```
-mem   force a temporary one
```

Standard

```
-s -v   standard and version
```

Data

```
-d   folder of datasets
-dxp   your define.xml
```

Rules

```
-r   run one rule
-er exclude rules
-lr   your own rule files
```

Dictionaries

```
--meddra --whodrug   your
licensed copies
```

Report

```
-of   XLSX, JSON or CSV
-o   output path
```

`--cdisc` runs the original CDISC pandas engine, which isn't maintained in this version. For the SEND/TIG engine, use CDISC's repository: **github.com/cdisc-org/cdisc-rules-engine**

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Live demo: CORE on a laptop

```
$ python core.py validate \
    -s sdtmig -v 3-4 \
    -d path/to/sample_study

[████████████--------] 53%
```

1. **Run**
   One validate command on a sample SDTM study
2. **Watch**
   A progress bar in the terminal
3. **Read**
   Open the report: summary, details, rules

Everything you see runs on a standard laptop, with nothing else to install.

Inside the report: five sheets

Conformance Details	Dataset Details	Issue Summary	Issue Details	Rules Report
When it ran, how long, and every version used	Every dataset: label, location, size, number of records	Issues per dataset and rule message: start here	One row per issue found	The run status of every rule selected

Report output options: add `-of JSON` or `-of CSV` for machine-readable output.

Every rule accounted for

Four statuses in the Rules Report

ISSUE REPORTED	The rule ran and found issues, listed in Issue Summary and Issue Details
SUCCESS	The rule ran and found no issues
SKIPPED	Nothing in scope, or an input such as define.xml wasn't given
EXECUTION ERROR	The rule couldn't finish

One status per rule

The most important result across datasets: EXECUTION ERROR > ISSUE REPORTED > SUCCESS > SKIPPED

The Reason column

Explains every SKIPPED and EXECUTION ERROR rule, naming the datasets

Built and tested by the community

Your feedback keeps making it better: report anything that looks off on GitHub.

Open-source is great, but scale when you need to

Try it yourself: CORE

- Free and open source
- Runs at home, on your own machine
- All SDTM and FDA Business Rules
- Designed for submissions up to ~1.5 GB

Scale it: Verisian platform

- Fully integrated, hosted CORE engine
- Built for production-sized submissions
- Traceability from every finding to data and code
- Continuous validation as your study evolves
- Part of a full submission analysis platform

Found a bug? Open an issue at github.com/verisianHQ/cdisc-rules-engine/issues

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Takeaways

All SDTM and FDA rules

621 Open Rules for SDTMIG 3.2 to 3.4, in one release

Try it today

An open engine that runs on your own machine – full open-source validation, no extra software required

More coming soon; get involved!

More rules are on the way! Stay tuned for ADaM and Define-XML, and get involved to help us write and review rules

Verisian Engine (SDTM, FDA): github.com/verisianHQ/cdisc-rules-engine

Rules, tests and evidence: github.com/verisianHQ/core-contributor

CDISC engine (TIG, USDM, SEND): github.com/cdisc-org/cdisc-rules-engine

What Remains & How to Get Involved

In Development

Standard	Status	Notes
SENDIG v3.1.1	Authoring/Testing	Existing SEND rules can be run on CORE V0.17.1 but have not been fully validated
Nonclinical FDA Business Rules	Authoring/Testing	27 FDA Business Rules remain
ADaM v1.1, 1.2, 1.3	Authoring/Testing	81% authored, to be reviewed
Define-XML v2.1	Specifications	Specification drafted, to be finalized

How to Get Involved

- Industry Pilot (TBD)
  - Governance group to manage an industry pilot that runs CDISC Open Rules on production study data and compares the results with current validation tools
  - Details will be shared as the pilot takes shape

- Rule Authoring
  - Ability to install necessary software (Git and VSCode) on your machine
  - Basic familiarity with Conformance Rules
  - Familiarity with GitHub, VSCode, and YAML
  - Sign up at www.cdisc.org/volunteer

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The Future Machine-Readable Rule Model

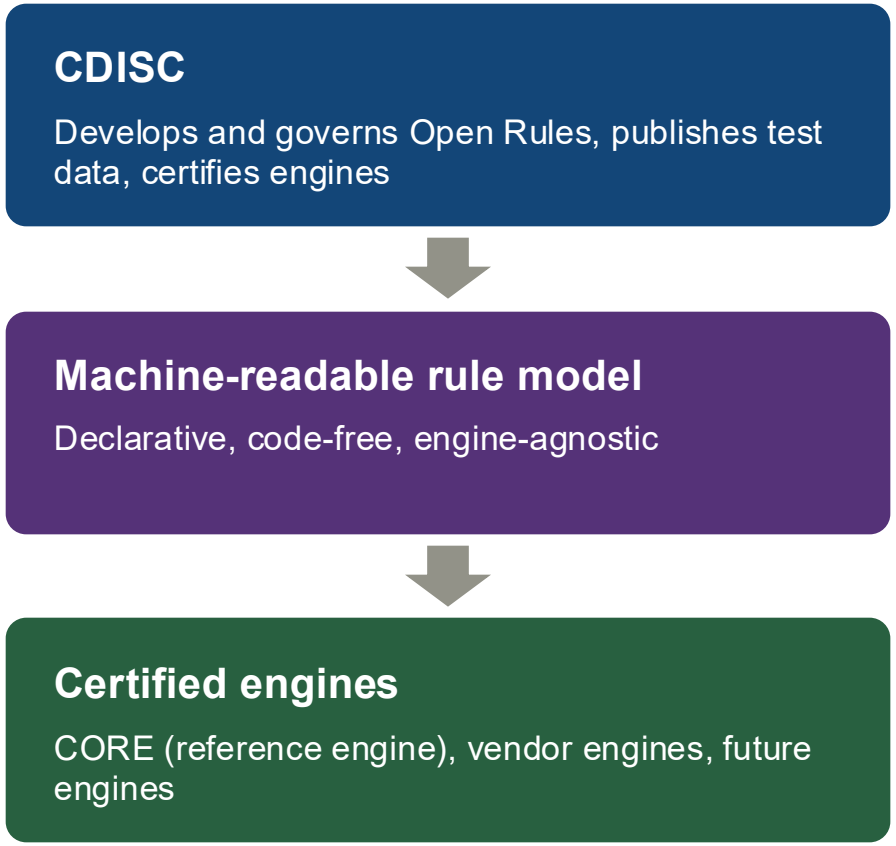
What it means and how to participate

Where we're heading: Open Rules any engine can run

Separate the rule model from the execution engine

Today

- Rules include engine-specific code (Python or SQL)
- CORE is required to run them
- New rule types need engine changes
- Authoring takes programming skills



Future

- Declarative rules: structured fields from a controlled vocabulary, no code
- Authored in a simple form-based tool
- Run by any certified engine with the same outputs

Same Open Rules. Same expected outputs. Any certified engine.

Short, mid, and long term

This release is a transition point, not a finish line



Now

November 2026

- CORE V1.0 released
- SDTMIG v3.2, 3.3, 3.4 and FDA Business Rules
- USDM v3.0, v4.0 and TIG v1.0 rules run on CORE V0.17.1
- ADaM and SEND rule work continues

Q4 2026

Short term

- Open Rules governance group formed
- Aligned with the USDM governance model

Q1 2027

Mid term

- Industry pilot on production study data
- Results compared with current validation tools

2027 and beyond

Long term

- Machine-readable rule model
- Form-based rule authoring
- Certified engines

Governance, pilot, and regulators

Governance group

- Forming now with those involved in Open Rules and CORE
- Guides the roadmap for remaining rule packages
- Shapes the rule model and engine certification
- Owns how community feedback is reviewed

Industry pilot

- Organized by the governance group, Q1 2027
- Run Open Rules on production study data
- Compare results with your current tools
- This is where structured feedback comes in

Regulators

- FDA Business Rules already published as open, executable rules
- Active conversations with other regulators
- Goal: one open rule set industry and regulators can both inspect

Stay involved: volunteer at cdisc.org/volunteer and watch for pilot details as the governance group takes shape

Questions?



cdisc Education

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