



Introduction to CDISC CORE

CDISC DEUN UG TC, 21-July-2023



www.mainanalytics.de

CDISC - Resources



COSA:
CDISC Open
Source Alliance

„CORE is a COSA project“

The screenshot shows the CDISC website navigation menu. The 'Resources' link is circled in red. Under the 'Resources' section, the 'CORE' link is also circled in red. The menu includes the following categories and links:


- cdisc** logo
- Navigation: New to CDISC, Standards, Education, **Resources**, Events, Membership, Members Only
- News**: News, What's New, For the Press, Video Library
- Global**: Americas, Africa, Asia, Australia, Europe
- Translations**: Chinese, Japanese
- Stakeholders**: Global Regulatory, Requirements, Cases for Clear Data, Partner Organizations, 3C, User Networks
- Volunteering at CDISC**: Volunteer Spotlight, Become a Volunteer
- Services**: ODM Certified Products, ODM Benefits and Rates, Become ODM Certified
- COSA**: **CORE**, OAK
- TMF Reference Model**: TMF Reference Model website, Become a TMF Volunteer
- Knowledge Base**: Articles, Examples Collection, Known Issues, eCRF Portal
- CDISC Primer**
- Guiding Principles**

CORE – CDISC Open Rules Engine

Home / CORE

CORE

Overview Program Highlights Program Governance Participate Presentations FAQ CORE on GitHub



Latest page content update: 24 Nov 2022

Page Note:

The CORE project originated as a traditional CDISC project with planning and volunteer/collaborator recruitment during spring & summer 2021 and formal kickoff in Sept 2021. During summer 2022, CDISC transitioned CORE development to an open-source framework. This page (tab) describes the project goals, objectives, and high-level roadmap; Please see the Program Governance page (tab) for description of the open-source governance framework. Please see the Planning & Status page (tab) for the latest CORE activity, which is now guided by the open-source CORE Roadmap Board.



Development of open-source software for the global clinical research community to test study data for conformance to CDISC standards as well as to regulatory and sponsor-specific conformance rule sets.

Why?

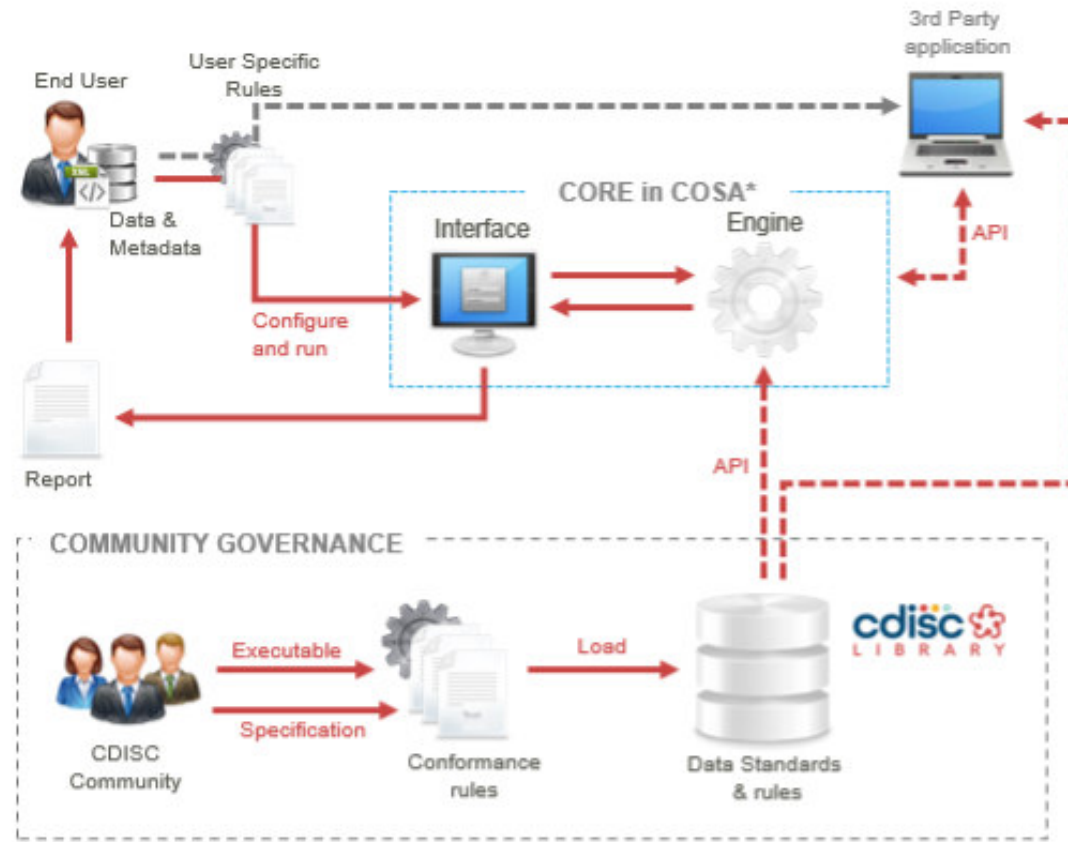


- Create a set of unambiguous, executable **conformance rules** for each CDISC standard
- Ensure consistency across **conformance rule** implementations
- Expedite availability of **conformance rules** for new standards
- Create **rules** vetted by the CDISC standard development teams
- Develop an open-source **engine** that serves as a reference implementation
- Publish **rules** in CDISC library
- Release of open-source **engine** under COSA



Development of conformance rules and engine

Project Concept



History: MVP Engine



- Presentation of the CORE Minimum Viable Product (MVP) Engine early evaluation version on CDISC EU Interchange 2022
- The MVP Engine was previously available via the CORE web page
- Provided with a basic user interface (UI) to allow users to quickly and easily run the engine to provide early feedback on the engine functionality to the CORE team

CDISC CORE – MVP Engine Demonstration

(no longer available)



CDISC Open Rules Engine

The screenshot shows the CDISC CORE MVP Engine Dashboard. On the left is a navigation sidebar with the following items: Dashboard, Conformance Validator, Rule Editor, Plugin, View My Studies, Manage My Rule Sets, and Help. The main content area has a blue header with the text "Welcome to CDISC CORE". Below the header are three large white cards: "Conformance Validator" (with a checkmark icon and description: "Validate your study with the most recent Conformance rules from the CDISC Library"), "Rule Editor" (with a gear icon and description: "Create you own rules with the Rule Editor"), and "Plugin" (with a pencil icon and description: "Create your own Plugin and use it within CORE"). Below these cards is a "Recent Studies" section with a refresh icon and a "See all" link. It contains a table with the following data:

| Study | Data Bundle | Standard | Last Validation Date ↓ |
|---------------|---------------|----------|------------------------|
| CDISCPILLOT01 | Issues | SDTM | 2022-04-22T19:32:09 |
| CDISC-TEST | Original Data | SDTM | 2022-04-20T08:33:23 |
| CDISCPILLOT01 | Clean Data | SDTM | 2022-04-14T15:17:56 |

At the bottom right of the table is a pagination indicator "1-3 of 3" with left and right arrows. To the right of the "Recent Studies" section is a "Resources" section with a link to "User Manual".



View My Studies

(MVP Engine - no longer available)

Dashboard / View My Studies

View My Studies

Search

^ Collapse All + Add Dictionaries + Add Study

CDISCPIL0T01 Therapeutic area: Alzheimer's Disease Phase II Client: CDISC + Add Bundle **View** Delete ^

Data Bundle Issues SDTM

Last validation date: 2022-04-22T19:32:09

Validate

Data Bundle Clean Data SDTM

Last validation date: 2022-04-14T15:17:56

Validate

CDISC-TEST Therapeutic area: Endocrinology Phase III Client: CDISC + Add Bundle View Delete ^



Conformance Validator

(MVP Engine - no longer available)

Dashboard / Conformance Validator / Choose Datasets

Choose Datasets

CDISCPIL0T01

Data Bundle: Issues
Last validation date: 2022-04-22T19:32:09

Datasets

| <input checked="" type="checkbox"/> | Dataset ↑ | Label | # Records | Size |
|-------------------------------------|-----------|--------------------|-----------|---------|
| <input checked="" type="checkbox"/> | AE | | | 21.4 kB |
| <input checked="" type="checkbox"/> | CM | | | 19.2 kB |
| <input checked="" type="checkbox"/> | DD | Death Details | | 4.0 kB |
| <input checked="" type="checkbox"/> | DI | Device Identifiers | | 16.4 kB |



Conformance Validator

(MVP Engine - no longer available)

Dashboard / Conformance Validator / Configure Conformance Rules

Configure Conformance Rules

Data Model: Model IG Version: Publisher:

My Rule Set Save Rule S

Conformance Rules

Rule Type Rule Severity

| <input checked="" type="checkbox"/> | Rule ID | Rule Type | Description | Version | Rule Severity |
|-------------------------------------|---------------------|----------------|---|---------|---------------|
| <input checked="" type="checkbox"/> | CDISC.SDTMIG.CG0007 | Value Presence | Raise an error when the date portion of --DTC is an incomplete date and the date portion of DM.RFSTDTC is an incomplete date, but --DY is not empty | 1.0 | Error |
| <input checked="" type="checkbox"/> | CDISC.SDTMIG.CG0008 | Value Presence | Raise an error when --TPTREF is empty, but --ELTM is not empty | 1.0 | Error |
| <input checked="" type="checkbox"/> | CDISC.SDTMIG.CG0009 | Range & Limit | Raise an error when EPOCH is not in TA.EPOCH | 1.0 | Error |
| <input checked="" type="checkbox"/> | CDISC.SDTMIG.CG0026 | Range & Limit | Trigger error when --TPTREF = null and --RFTDTC is populated | 1.0 | Error |
| <input checked="" type="checkbox"/> | CDISC.SDTMIG.CG0027 | Range & Limit | Trigger error when --SCAT is not null and --SCAT is equal to --CAT | 1.0 | Warning |

Versions

CDISC CT: UNII: MED-RT:

Dictionaries

MedDRA: WHODD: SNOMED:



Issue Reporting

(MVP Engine - no longer available)

CDISCPIL01 / Issues / 2022-04-24T14:58:51 ↓

Issue Summary Issue Details Rules Reports

Search

| Dataset ↑ | Rule ID | Error Message | Severity | # Issues | Explanation |
|-----------|---------------------|--|----------|----------|---------------------------------|
| AE | CDISC.SDTMIG.CG0041 | At least one of the Seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE) = "Y", but AESER = "N" or empty. | Error | 1 | |
| AE | CDISC.SDTMIG.CG0042 | If AESER = "N" then none of the seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE) could be equal to "Y". | Warning | 3 | |
| AE | CDISC.SDTMIG.CG0050 | AEDECOD should be populated when AEPTCD is populated | Error | 1 | |
| AE | CDISC.SDTMIG.CG0389 | AESCONG is completed, but not equal to "N" or "Y" | Error | 1 | This issue needs to be resolved |



Issue Reporting

(MVP Engine - no longer available)

Dashboard / View My Studies / View details / Report details

CDISCPILLOT01 / Issues / 2022-04-24T14:58:51

Issue Summary **Issue Details** Rules Reports

Search

| Rule ID ↑ | Error Message | Severity | Dataset | USUBJID | Record | Sequence | Variable(s) | Value(s) |
|---------------------|---|----------|---------|----------|--------|----------|----------------|------------|
| CDISC.SDTMIG.CG0008 | FTPTREF is empty and FTELM is not empty | Error | FT | CDISC003 | 958 | 278 | FTELM, FTPTREF | PT30M, |
| CDISC.SDTMIG.CG0008 | FTPTREF is empty and FTELM is not empty | Error | FT | CDISC003 | 959 | 279 | FTELM, FTPTREF | PT30M, |
| CDISC.SDTMIG.CG0008 | FTPTREF is empty and FTELM is not empty | Error | FT | CDISC003 | 960 | 280 | FTELM, FTPTREF | PT30M, |
| CDISC.SDTMIG.CG0009 | EPOCH is not in TA.EPOCH | Error | DS | CDISC002 | 6 | 3 | EPOCH | TREATMENT1 |



Issue Reporting

(MVP Engine - no longer available)

Dashboard / View My Studies / View details / Report details

CDISCPIL0T01 / Issues / 2022-04-24T14:58:51

Issue Summary Issue Details **Rules Reports**

Search

| Rule ID ↑ | Message | Status |
|---------------------|--|---------|
| CDISC.SDTMIG.CG0007 | The date portion of --DTC is not complete date or the date portion of DM.RFSTDTC is not complete date, but --DY is not empty | Success |
| CDISC.SDTMIG.CG0008 | --TPTREF is empty and --ELTM is not empty | Success |
| CDISC.SDTMIG.CG0009 | EPOCH is not in TA.EPOCH | Success |
| CDISC.SDTMIG.CG0026 | --RFTDTC is populated when --TPTREF is null | Skipped |



Issue Reporting

(MVP Engine - no longer available)

| A | B |
|---------------------|--------------------------------------|
| Conformance Details | |
| Study | CDISCPIL0T01 |
| Bundle | Issues |
| Report Generation | 2022-04-24T14:58:51 |
| Total Runtime | 166 seconds |
| Transaction ID | 71f9b9fa-df84-4f71-b519-a1cd477b81db |
| Study Details | |
| Therapeutic Area | Alzheimer's Disease |
| Phase | II |
| Client | CDISC |
| Study Start Date | 2012-10-06 |
| Bundle Details | |
| Standard | SDTM |
| Version | V3.4 |
| CT Version | 2020-03-27 |
| Define-XML Version | 2.1 |
| UNII Version | Not configured |
| Med-RT Version | Not configured |
| MedDRA Version | Not configured |
| WHODRUG Version | Not configured |
| SNOMED Version | Not configured |

Today: CORE on GitHub



- The CORE Engine Reference Implementation on GitHub is an advancement over the CORE Minimum Viable Product (MVP) engine early evaluation version
- The GitHub-based engine is updated to process additional rule syntax (YAML) engaged to handle new processing conditions that were encountered as the CORE team developed additional rules
- The GitHub-based engine is written in Python and provided with a **command line interface (CLI)**

CORE on GitHub



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CORE

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CORE on GitHub

Latest page content update: 01 Mar 2023

CORE Engine Reference Implementation in GitHub

The CORE Engine Reference Implementation is the current version of the Engine. The CORE Engine Reference Implementation has been transferred to a GitHub-based environment with its provision on GitHub. The GitHub-based Engine is:

- Provided as open source with the permissive MIT license
- Registered with the [CDISC Open-Source Alliance \(COSA\)](#)
- Available to users for free
- Provided with a command line interface (CLI)
- Accessed at the GitHub [CDISC-rules-engine](#) repository, including special instructions in the [Readme](#) file

CORE on GitHub



cdisc-org / cdisc-rules-engine Public

<> Code Issues 84 Pull requests 4 Discussions Actions Projects 1 Wiki Security Insights

main 66 branches 51 tags Go to file Code

nhaydel Add new keys to perform_rule_operations and fix regression tests (#442) e87c-f7a 16 hours ago 534 commits

| | | |
|--------------------|---|--------------|
| .github | Add new keys to perform_rule_operations and fix regression tests (#442) | 16 hours ago |
| TestRule | ISS 273: Crosscheck values against Define XML Codelists (#423) | |
| cdisc_rule_tester | Endpoint supports define.xml (#356) | |
| cdisc_rules_engine | Add new keys to perform_rule_operations and fix regression tests (#442) | |
| resources | ISS 274 - New rule type Value Check against Define XML VLM (#436) | |
| scripts | Convert remaining file name manipulation to os file path manipulation | |
| tests | Add new keys to perform_rule_operations and fix regression tests (#442) | |

☰ README.md

Supported python versions

python 3.7 python 3.8 python 3.9 python 3.10

cdisc-rules-engine

Open source offering of the cdisc rules engine

Quick start



CORE on GitHub

Example of a test implementation

- Implementation of a virtual test desktop with read/write access to set-up a Python Environment and to download executable version of the cdisc rules engine from github.
- Open Git CMD window

On Git CMD, from the desired folder:

```
git clone https://github.com/cdisc-org/cdisc-rules-engine.git  
git clone https://github.com/<user>/cdisc-pilot-submission.git  
cd cdisc-rules-engine  
python3.10 -m venv .venv  
.\.venv\Scripts\activate  
.\.venv\Scripts\python.exe -m pip install -r requirements.txt  
.\.venv\Scripts\python.exe -m pre_commit install  
.\.venv\Scripts\python.exe -m pytest tests/unit/
```

```
.\.venv\Scripts\python.exe core.py validate -s sdtmig -v 3-4 -d ../cdisc-pilot-submission/definesdtm
```

=> Result: issue report (XLSX format)

CORE Presentations

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CORE

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The following are links to CORE presentations from the 2023 CDISC Europe Interchange:

- Title: [CDISC Conformance Rules and the CORE Engine: Progress and Roadmap](#)
- Presenter: Peter Van Reusel, Chief Standards Officer, CDISC
- Date: 27 April 2023

- Title: [How to Extend and Run CORE](#)
- Presenter: Sam Hume, VP, Data Science, CDISC
- Date: 27 April 2023

- Title: [CORE](#)
- Presenter: Amy Palmer, Head of Data Standards, CDISC
- Date: 27 April 2023

Article:

[The CDISC Open Rules Engine: Open-Source Software for Clinical](#), an article in Clinical Leader by Sam Hume, VP, Data Science, CDISC

CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

Rules Specifications and Executable Rules: Overview



Conformance Rule Specification Development

Human-readable Specification

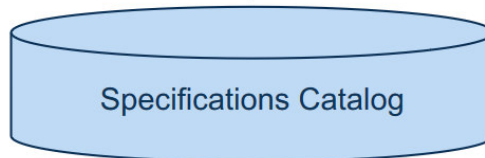
| Rule ID | SDTMIG Version | Rule Version | Class | Domain | Variable | Condition | Rule |
|---------|----------------|--------------|-------|--------|----------|--------------------------------|----------------|
| CG0225 | 3.4 | 1 | ALL | ALL | VISITDY | VISITNUM is NOT in TV.VISITNUM | VISITDY = null |

| Document | Section | Item | Cited Guidance |
|----------|---------|------|---|
| IG v3.4 | 4.4.5 | | VISITDY must not be populated for unplanned visits, since VISITDY is, by definition, the planned study day of visit, and since the actual study day of an unplanned visit belongs in a --DY variable. |

Authoring Sources:

- CDISC Standards
- Regulatory Authority Validation Rules
- Community proposals - curated per CDISC Operating Procedure (COP)

Centralized



CORE Rule Development

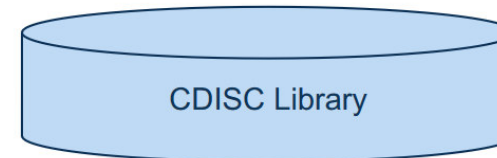
Executable Rule (YAML) in CORE Rule Editor

```

1 Core:
2   id: CDISC-CDRTR-000225
3   namespace: "1"
4   authority: "1"
5   organization: CDISC
6   description: "Trigger error if VISITDY is populated when VISITNUM is not in TV."
7   references:
8     - id: CG0225
9       version: "1"
10
11 ---
12 Version: "2.0"
13 Severity: "Error"
14 severity: "Warning"
15 Rule Type: "Value Presence"
16
17 scopes:
18   - End Date
19   - Domain: "ALL"
20   - End Date: "ALL"
21   - Start Date: "ALL"
22   - Standards:
23     Name: "SDTMIG"
24     Version: "3.4"
25
26 operators:
27   name: "TV"
28   id: "VARIABLE_EXISTS"
29   name: "VISITNUM"
30   operator: "EXISTS"
    
```

Rule developed and tested in CORE Rule Editor and CORE Engine, per CDISC COP

Publish



CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

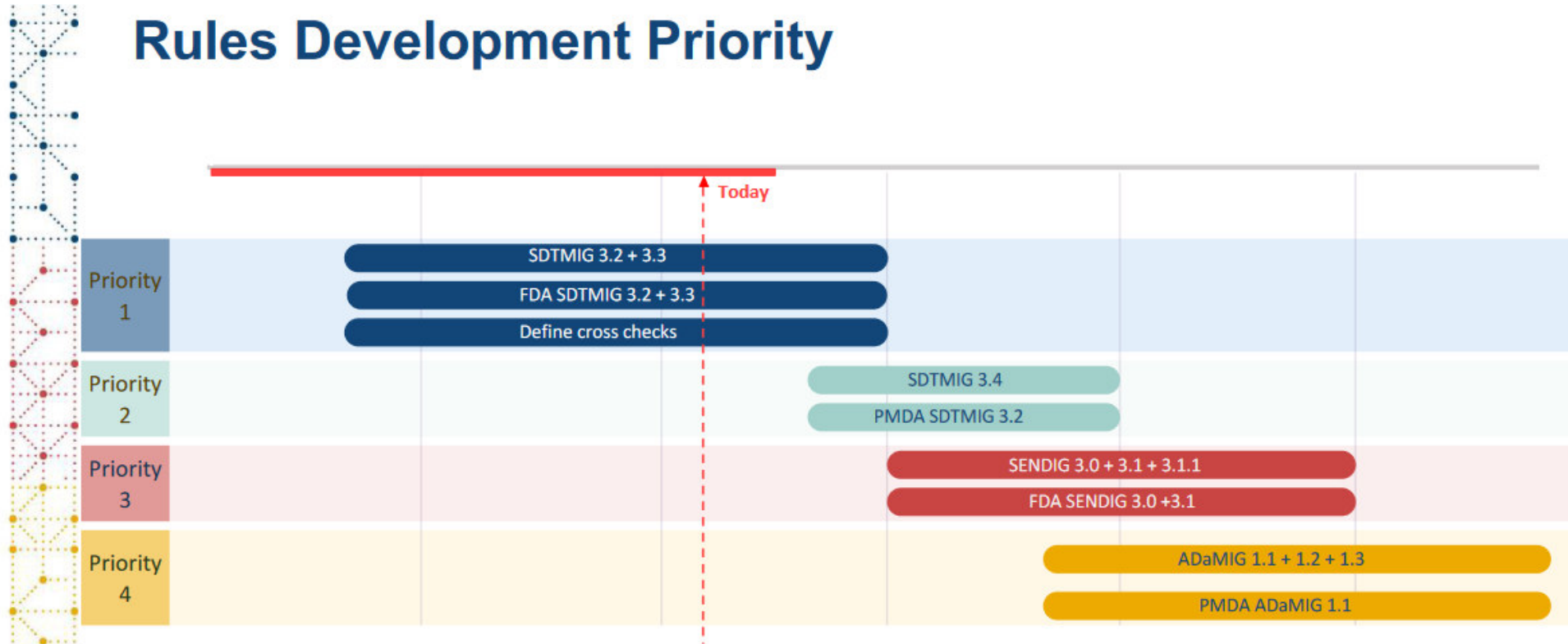
Rules Development Progress

| Components | Status | | | | | | | | | | |
|-----------------------------|-------------|------------|-----------|--------------|----------------|------------------|------------|-------------|--------------------|----------------|-------------|
| | OPEN | DONE | BLOCKED | UNIT TESTING | QC IN PROGRESS | READY TO PUBLISH | PUBLISHED | AWAITING QC | AUTHOR IN PROGRESS | BACK TO AUTHOR | T: |
| ADaMIG v1.0 | 314 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 321 |
| ADaMIG v1.1 | 419 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 426 |
| ADaMIG v1.2 | 591 | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 598 |
| ADaMIG v1.3 | 568 | 0 | 5 | 4 | 2 | 0 | 7 | 9 | 1 | 0 | 596 |
| FDA SDTMIG v3.2 | 493 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 493 |
| FDA SDTMIG v3.3 | 501 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 501 |
| FDA SENDIG DART v1.1 | 350 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 350 |
| FDA SENDIG v3.0 | 316 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 316 |
| FDA SENDIG v3.1 | 330 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 330 |
| FDA SENDIG v3.1.1 | 335 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 335 |
| FDA SENDIG-AR v1.0 | 466 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 466 |
| SDTMIG v3.2 | 279 | 37 | 14 | 0 | 3 | 0 | 74 | 0 | 5 | 4 | 416 |
| SDTMIG v3.3 | 295 | 48 | 14 | 1 | 4 | 0 | 78 | 0 | 5 | 4 | 449 |
| SDTMIG v3.4 | 7 | 60 | 51 | 10 | 4 | 0 | 272 | 2 | 35 | 3 | 444 |
| SENDIG v3.0 | 259 | 0 | 0 | 0 | 4 | 0 | 1 | 0 | 0 | 0 | 264 |
| SENDIG v3.1 | 174 | 2 | 2 | 3 | 4 | 9 | 1 | 96 | 11 | 1 | 303 |
| SENDIG v3.1.1 | 307 | 0 | 0 | 0 | 4 | 0 | 1 | 0 | 0 | 0 | 312 |
| SENDIG-DART v1.1 | 353 | 0 | 0 | 0 | 4 | 0 | 1 | 0 | 0 | 0 | 358 |
| Total Unique Issues: | 6357 | 147 | 86 | 18 | 29 | 9 | 456 | 107 | 56 | 12 | 7277 |

CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

Rules Development Priority



➔ *Timelines depend on community engagement*

CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

What does the CORE Engine do?

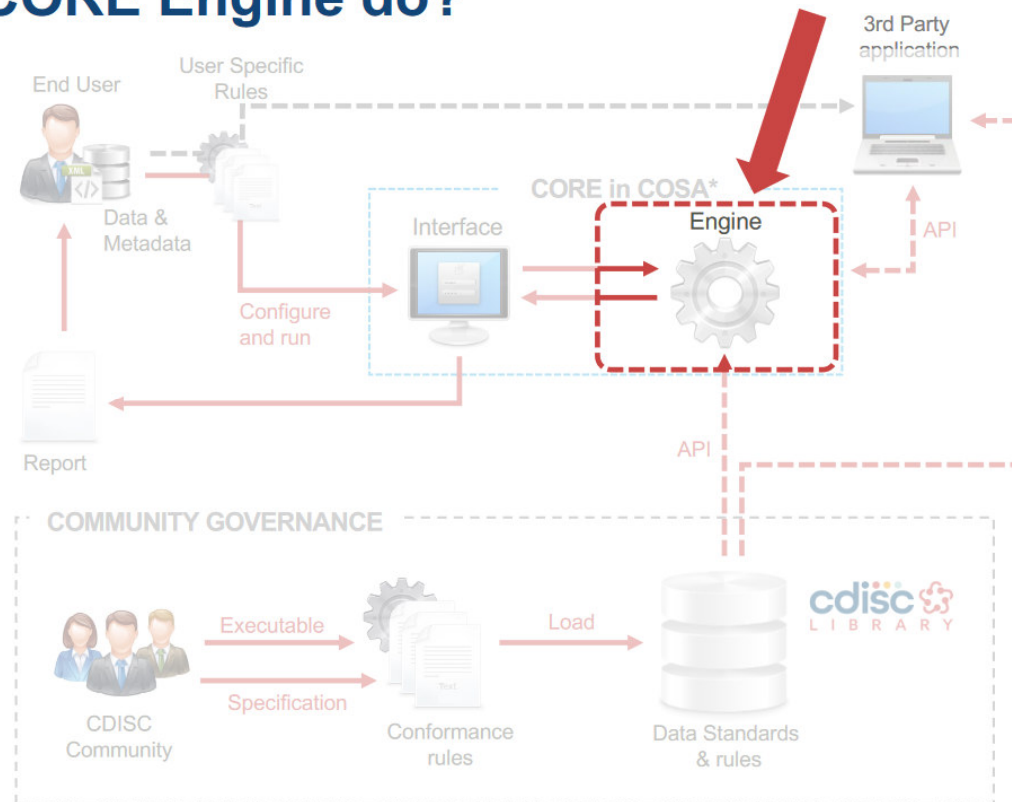
CORE Engine

Functionality:

- Executes CORE Rules (YAML) against clinical data and returns results
- Deployment agnostic
- Open-source, available in GitHub

Current focus:

- Process new YAML operators added to express new rules
- Process new clinical data formats
- Support Define xml cross-checking



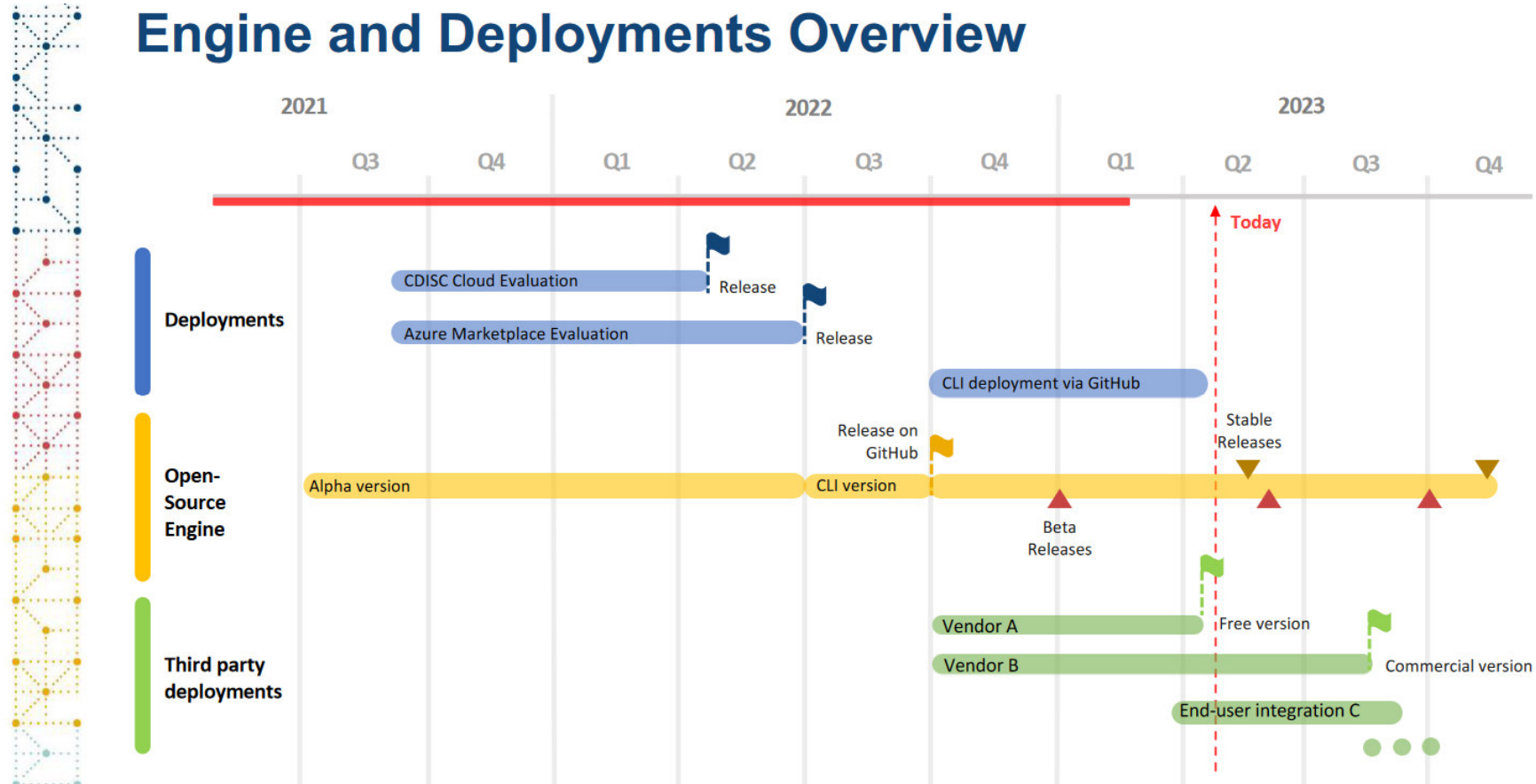
* CDISC Open-Source Alliance



CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

Engine and Deployments Overview



CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

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
- Multiple vendors are currently preparing an early-release desktop version
- First free, publicly available, vendor-provided CORE desktop version announced at this Interchange

 *Drive adoption*

CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

CORE Registered Solution Provider



- Program purpose

- For CORE vendors (solution providers)
 - A means to officially certify with CDISC that their CORE solutions correctly use the CORE Rules
- For CDISC
 - A means to treat all CORE vendors equally regarding
 - Certifying vendor solutions – by testing all solutions with the same “certification test package” – Rules, test data, and test run set
 - Informing the CDISC community of available vendor CORE solutions – by announcing every and only certified solutions
 - A means to achieve a level playing field re use of any Engine with the CORE Rules

- Testing for certification will include

- Generating results with CORE Rules and test study data reflecting an “average study”
- No system functionality testing

CORE presentations

CDISC Conformance Rules and the CORE Engine: Progress and Roadmap, Peter van Reusel

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*



Vendor Provided Desktop Application

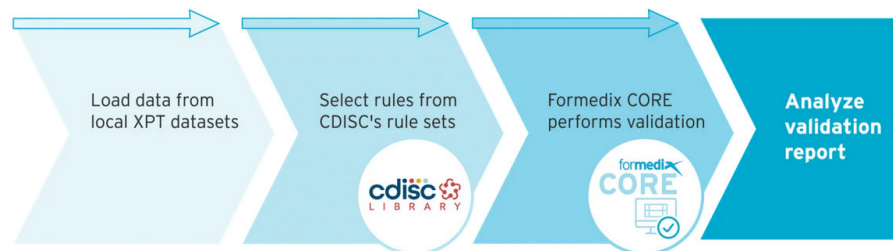
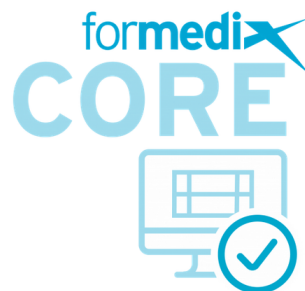
First free, publicly available, vendor-provided CORE desktop version announced at the interchange:

<https://www.formedix.com/formedix-core-cdisc-core-open-rules-engine/>

Introducing Formedix CORE: a free-to-use desktop app incorporating the CDISC Open Rules Engine

Formedix CORE is a free, downloadable Windows desktop application that allows you to validate datasets using the [CDISC Open Rules Engine \(CORE\)](#). The application provides an easy way to run validations on local data and identify standards conformance issues.

DOWNLOAD CORE





Thank you!

Questions?

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