PP15

The CDISC Open Rules Engine (CORE) Project

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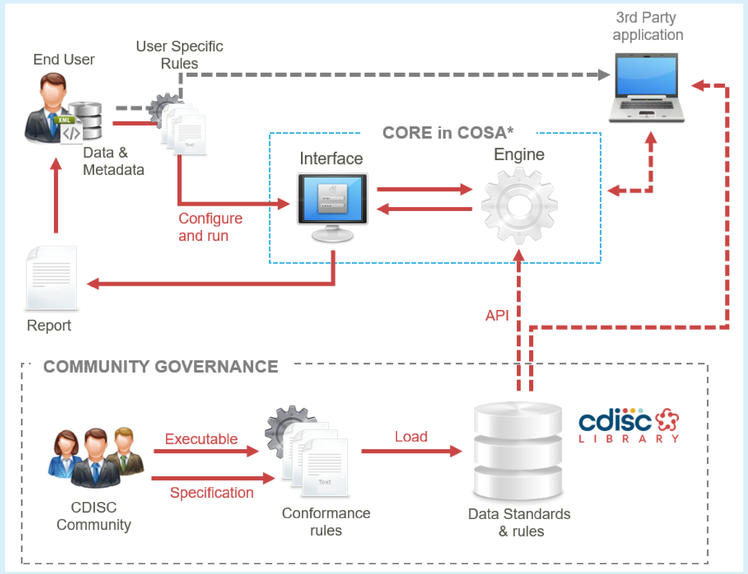
CORE Overview



CORE Engine Repository: github.com/cdisc-org/cdisc-rules-engine

CORE Rationale

1. Unambiguous, executable Conformance Rules - ensure each standard has a set of unambiguous, consistent, executable Conformance Rules

2. Community-based development – CDISC community reviews and improves Conformance Rules

3. Available as standards are published - expedite the availability of executable Conformance Rules for new Foundational Standards

4. Rules are part of the standards - create executable Conformance Rules vetted by the CDISC standards development teams

5. Open-source tooling - develop an open-source engine that serves as a Reference Implementation

CORE Conformance Rule Authoring

CORE Rule Development

Executable Rule (YAML) in CORE Rule Editor

```yaml
Core:
  Id: CDISC.SDTMIG.CG0225
  Version: '1'
Authority:
  Organization: CDISC
Description: Trigger error if VISITDY is populated when VISITNUM is not in TV.
References:
  - Origin: SDTM and SDTMIG Conformance Rules
    Rule Identifier:
      Id: CG0225
      Version: '1'
  - Version: '2.0'
Sensitivity: Record
Severity: Warning
Rule Type: Value Presence
Scopes:
  Classes:
    Include:
      - All
  Domains:
    Include:
      - All
  Standards:
    - Name: SDTMIG
      Version: '3.4'
Operations:
  - domain: TV
    id: $tv_visitnum
    name: VISITNUM
    operator: distinct
```

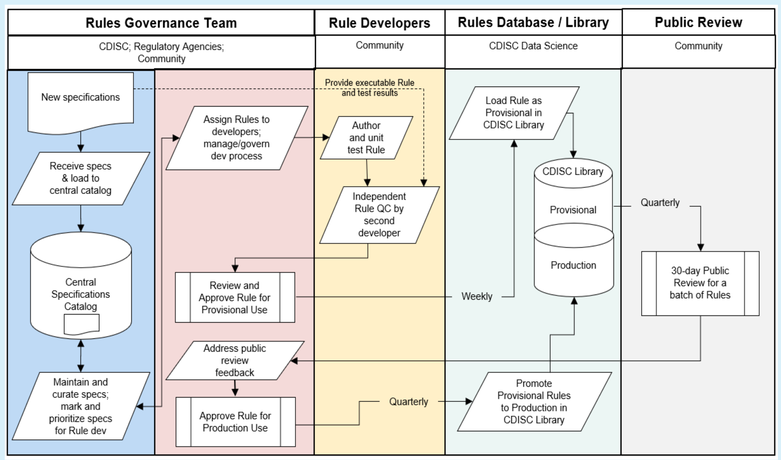
Rules developed and tested in CORE Rule Editor and Engine

Publish

CDISC Library

CORE Rule Editor: github.com/cdisc-org/conformance-rules-editor

CORE Conformance Rule Governance



Conformance Rules are available to all via the CDISC Library

Current CORE Release: github.com/cdisc-org/cdisc-rules-engine/releases/tag/v0.6.2

CORE Facts

1.CORE is extensible – it can be adapted to run different kinds of rules against different kinds of datasets on different platforms to create different kinds of reports

2.CORE is open-source and can be used for free - you have access to the code (MIT license) and, you can get executable versions of CORE for free

3.CORE has a community of providers – many providers are interested in providing products or services around CORE – including embedding CORE in their platforms

4.CORE is not just for submissions - CORE can be used in all phases of your research data lifecycle to test for data quality as well as standards conformance

CORE Reporting

	A	B
1	Conformance Details	
2	Data Location	c:\users\samhume\core\datasets\ae.xpt, c:\users\samhume\core\datasets\dm.xpt, c:\users\samhume\core\datasets\ds.xpt, c:\users\samhume\core\datasets\lb.xpt, c:\users\samhume\core\datasets\suppae.xpt
3	Report Generation	2023-03-23T13:01:08
4	Total Runtime	7.19 seconds
5		
6		
7	Bundle Details	
8	Standard	SDTMIG
9	Version	V3.4
10	CT Version	
11	Define-XML Version	
12	UNII Version	Not configured
13	Med-RT Version	Not configured
14	MedDRA Version	
15	WHODRUG Version	
16	SNOMED Version	Not configured

CORE Report:
- In Excel by default
- Placed in CORE folder
- Datetime stamp in name

	A	B	C	D	E	
1	Dataset	RuleID	Message	Severity	Issues	Explanation
2	AE	CORE-000022	At least one of the Seriousness criteria (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD or AESMIE) = 'Y', but AESER = 'N' or empty.		27	
3	AE	CORE-000206	AESTDTC is present in a Findings general observation class		1	
4	DM	CORE-000253	DTHFL is not 'Y' when AE.AEOUT is 'FATAL'.		9	
5	DS	CORE-000206	DSSTDTC is present in a Findings general observation class		1	
6	SV	CORE-000206	SVSTDTC is present in a Findings general observation class		1	
7	TS	CORE-000107	An appropriate subject identifier is not present. APID is required in all Associated Persons Data. In addition to STUDYID, DOMAIN, and TSSEQ being required for all domains based on one of the 3 general observation classes, one of USUBJID, APID, SPDEVID, or POOLID must also be present.		1	

Reporting content and format can be customized