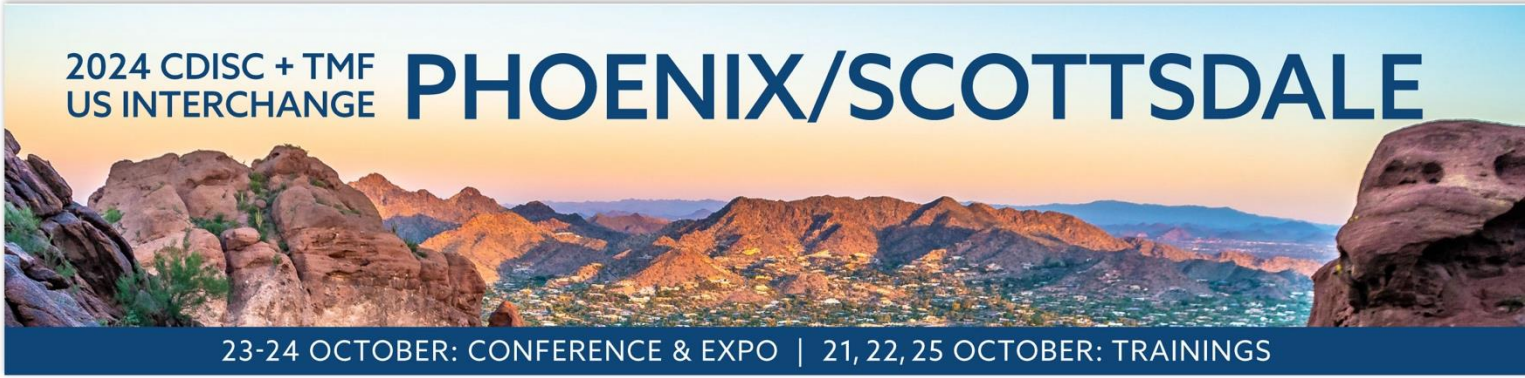


Bending the Rules: A Deep Dive into Custom Rule Creation with the Open Rules Project

Presented by Roman Radelicki, Head Data Technology, SGS Health Science

Meet the Speaker

Roman Radelicki

Title: Head Data Technology

Organization: SGS Health Science

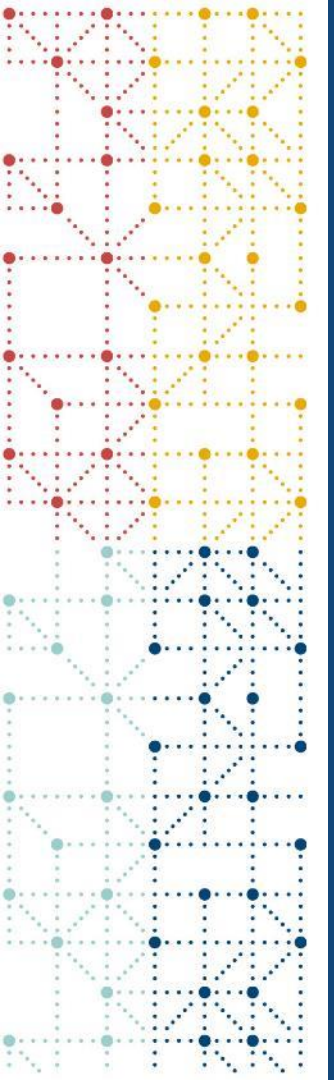
Roman Radelicki started his career as Programmer in 2006 and joined SGS in 2009. During his career at SGS he held several positions and became Head Data Technology in 2021. He is mainly responsible for managing the data engineering, data programming and data science teams, providing support to the different departments.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. About CDISC Open Rules
2. CDISC Open Rules: how does it work
3. Local custom rules with CDISC Open Rules
4. Who can create CDISC Open Rules and why should we
5. Creating custom CDISC Open Rules
6. Use cases
7. Suggestions – AI integration



About CDISC Open Rules

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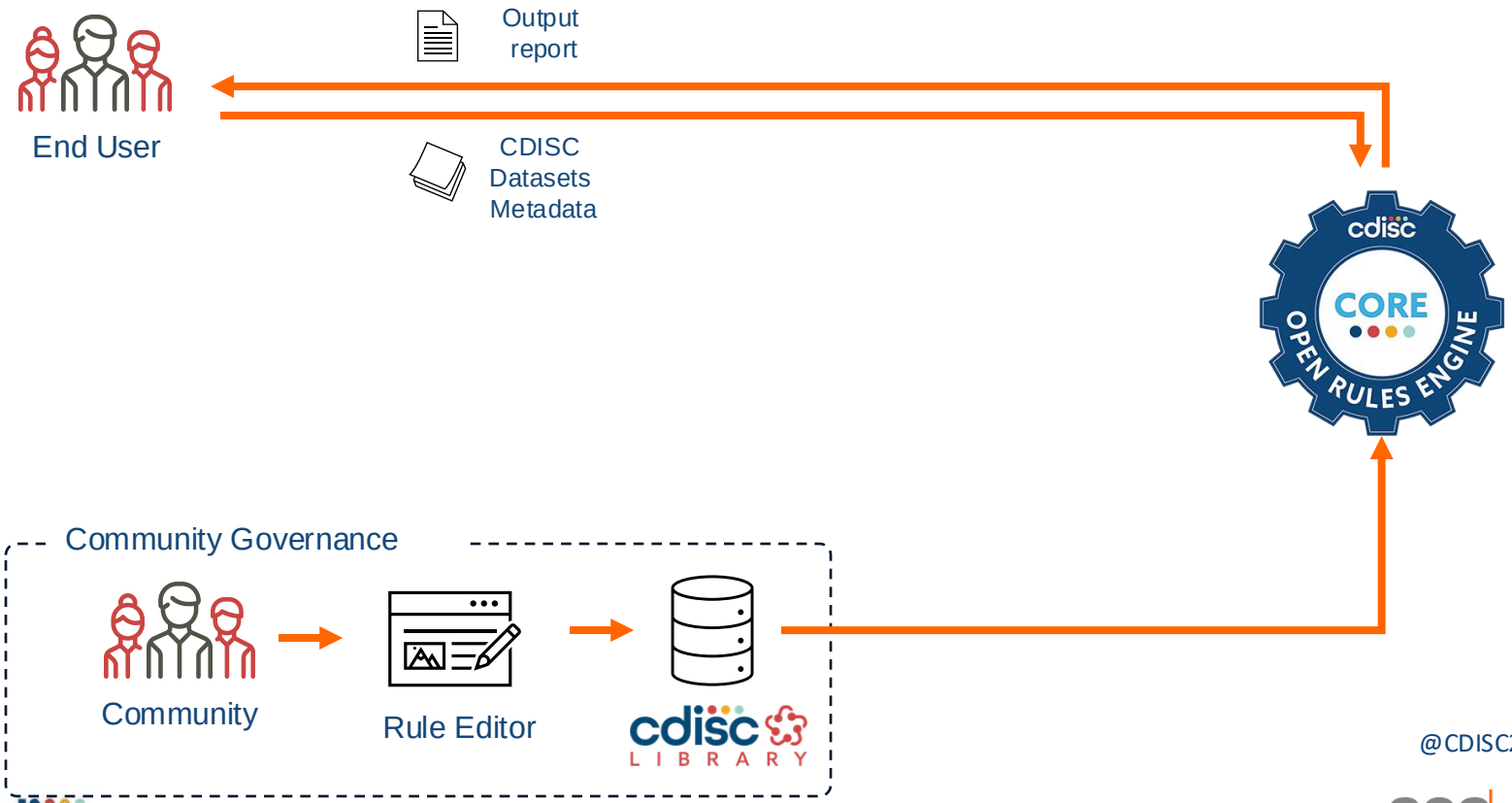
About CDISC Open Rules

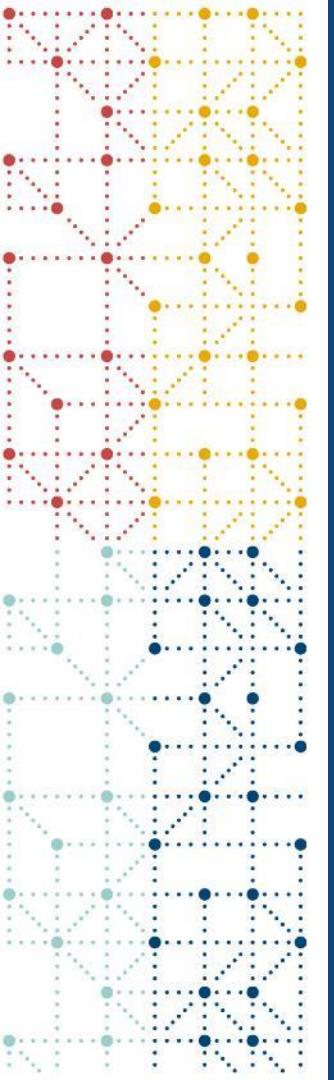
Rules

- CDISC governed – single source of truth
- Community driven
- Executable rules
- Submission ready
- Open-Source

CDISC Open Rules: How does it work?

CDISC Open Rules: How does it work?





Local custom rules with CDISC Open Rules

Can we create our own rules with CDISC Open Rules?

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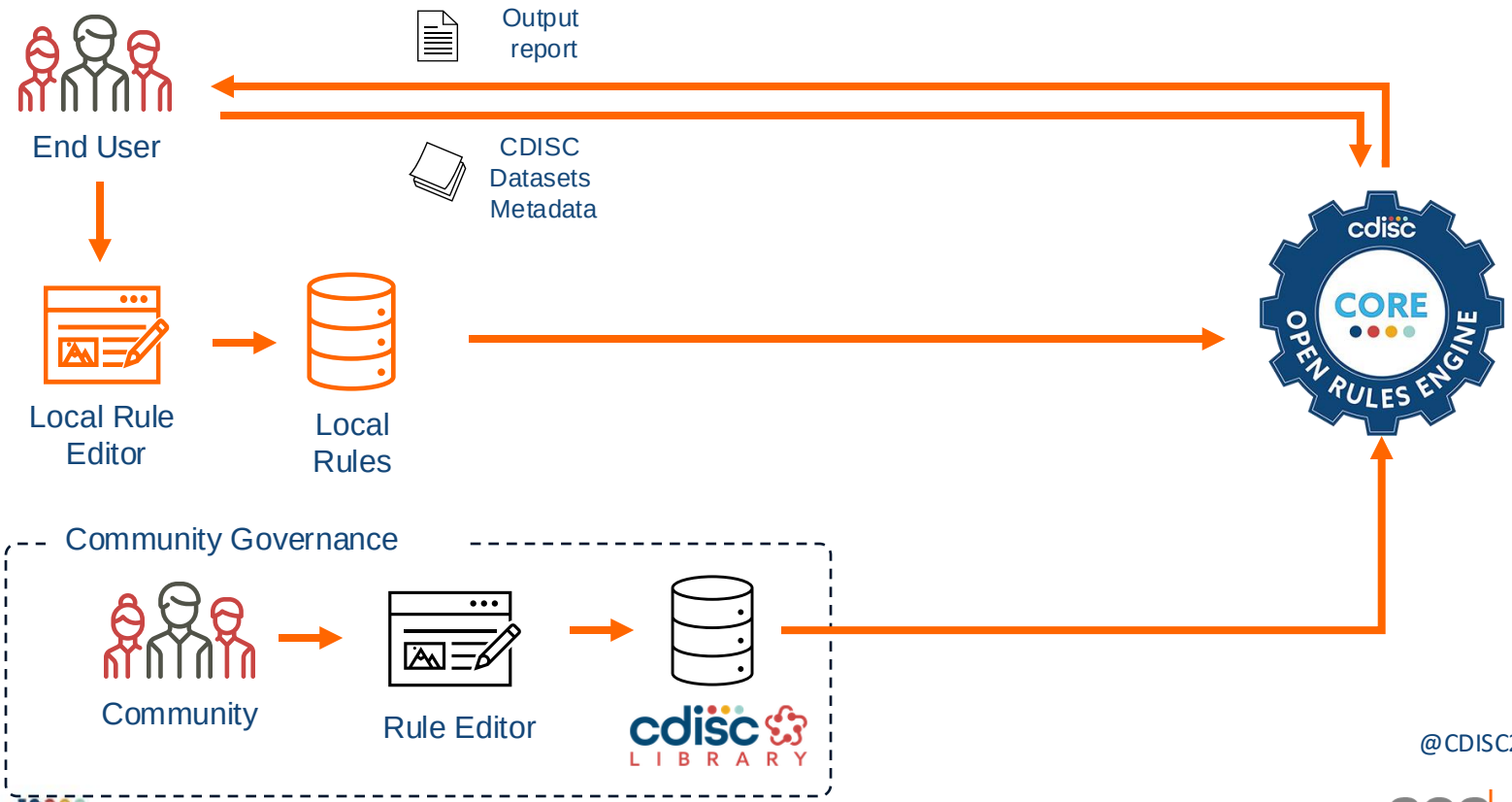
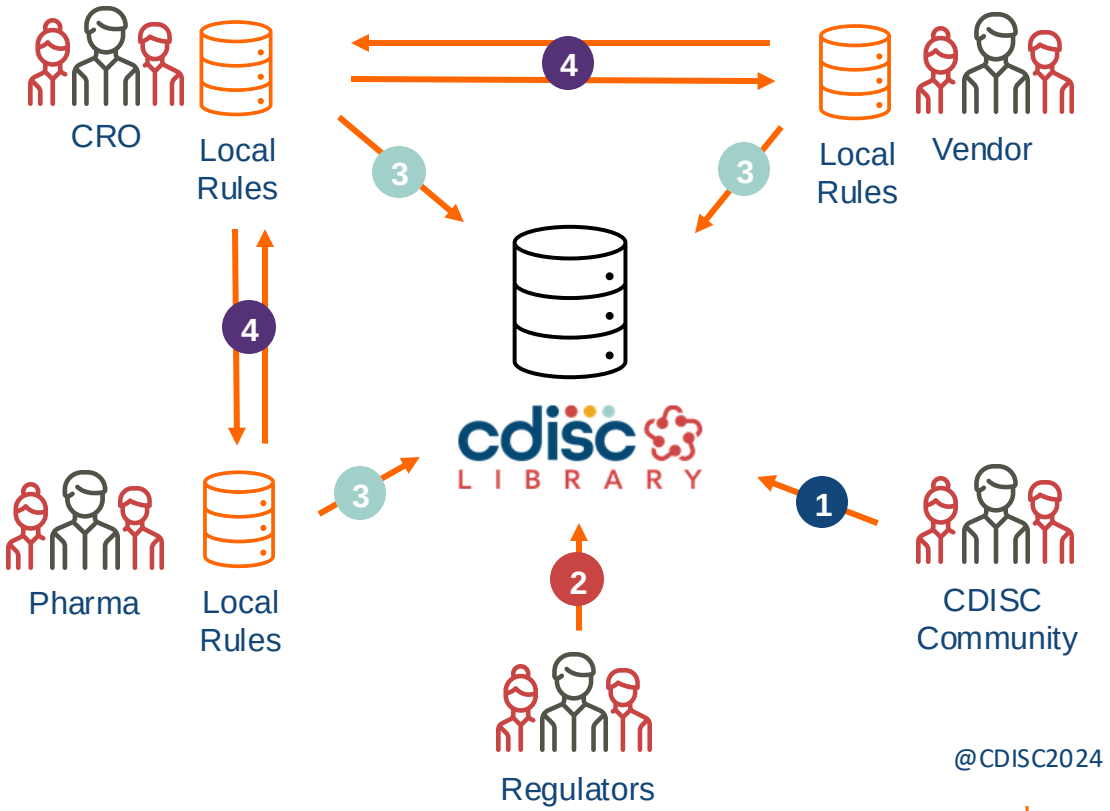
Developing custom rules with CDISC Open Rules



Who can create rules with CDISC Open Rules and why should we?

Who & Why?

1. CDISC rules governance
2. Collaboration CDISC / FDA
3. Contribution to CDISC rules
4. Transfer of custom rules



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Creating custom CDISC Open Rules

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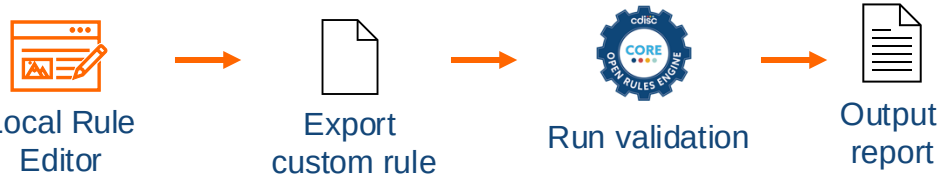
Creating custom CDISC Open Rules

Process flow:



Rule Editor

- Web application
- Written in TypeScript
- YAML
- Real-time syntax checking
- GitHub workflow provided

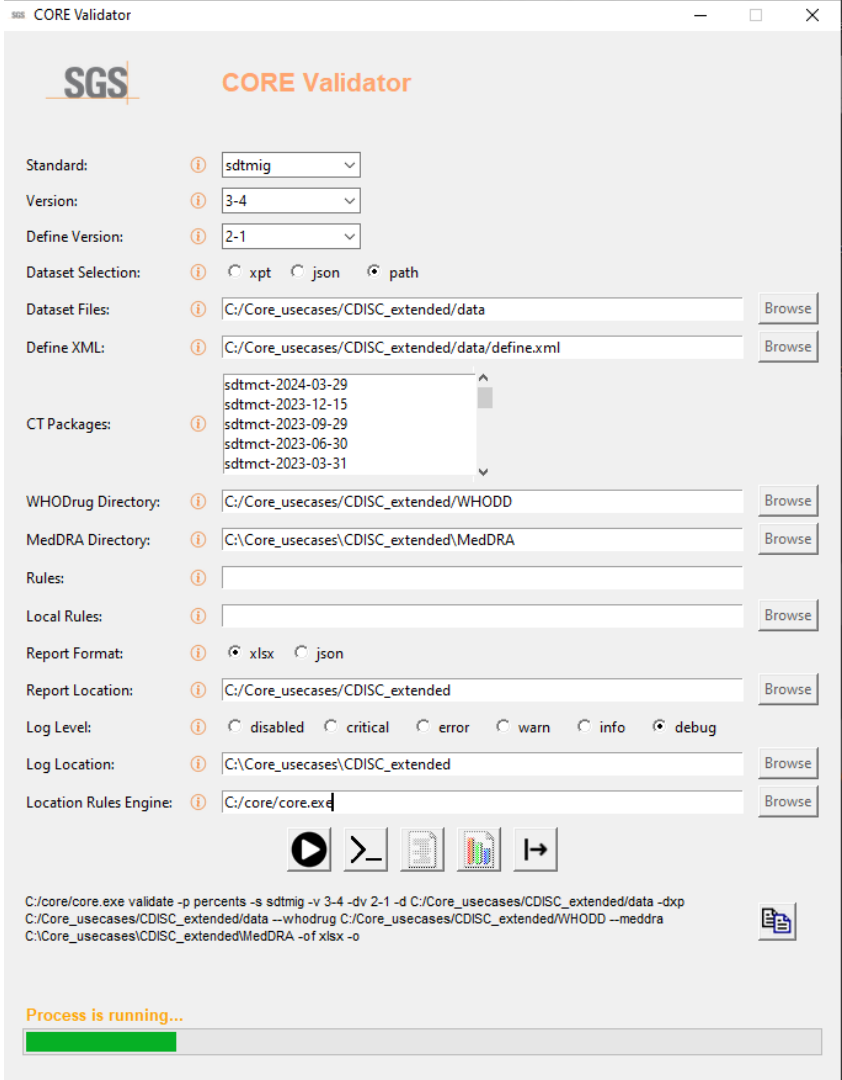
Rule Engine

- Download from GitHub
- Command line interface
  - integrate in existing process flows e.g. Nightly automatic conversion workflow
- CLI – UI interface for less tech-savvy people – SGS proof of concept

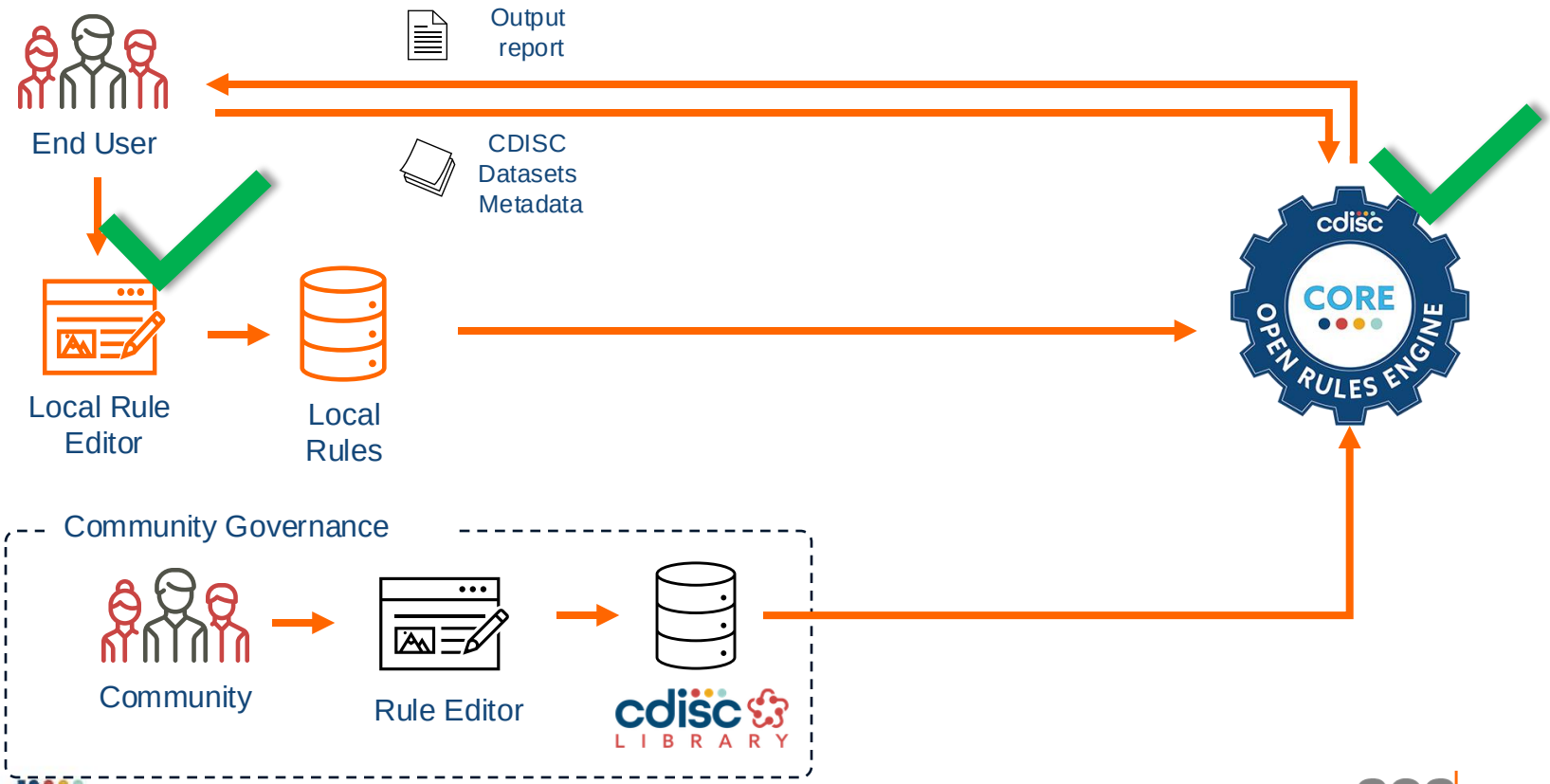
Creating custom rules

- CLI – **UI interface** for less tech-savvy people
  - SGS's proof of concept
  - Efficiency gain

```
C:/core/core.exe validate
-s sdtmig -v 3-4 -dv 2-1
-d C:/Core_usecases/CDISC_extended/data
-dxp C:/Core_usecases/CDISC_extended/data
-whodrug
C:/Core_usecases/CDISC_extended/WHODD
-meddra
C:/Core_usecases/CDISC_extended/MedDRA
-of xlsx
-o
C:/Core_usecases/CDISC_extended/core_report
_20240923103803
-l debug -p percents
```



Developing rules with CDISC Open Rules



Use Cases – custom CDISC Open Rules

Use Cases – Custom CDISC Open Rules

Q2 COSA Quarterly Spotlight Webinar:

- https://www.cdisc.org/core/authoring-and-running-your-own-rules

- Rule not currently included in the CDISC governed set
- Rule for data cleaning
- Rule for non-CDISC clinical data such as external vendor data

Use Cases – custom CDISC Open Rules

Data listings

Use case: data listings

- List all male subjects older than 40 and female subjects older than 41

```yaml
Check:
  any:
    - all:
      - name: AGE
        operator: greater_than
        value: 40
      - name: SEX
        operator: equal_to
        value: M
    - all:
      - name: AGE
        operator: greater_than
        value: 41
      - name: SEX
        operator: equal_to
        value: F
```

Use case: data listings

CORE-ID	Message	Dataset	USUBJID	Record	Variable(s)	Value(s)
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S001	1	AGE, SEX	42.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S014	7	AGE, SEX	42.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S024	9	AGE, SEX	48.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S033	13	AGE, SEX	45.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S034	14	AGE, SEX	55.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S039	16	AGE, SEX	41.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S047	19	AGE, SEX	48.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S048	20	AGE, SEX	44.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S049	21	AGE, SEX	43.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S052	23	AGE, SEX	51.0, M

Use case: data listings

- Current output file/structure not ideal
- Indications

USUBJID	AGE	SEX	IND_COUNTRY_BEL
SGS-DRG-00A-S001	42	F	*
SGS-DRG-00A-S002	42	M	
SGS-DRG-00A-S003	48	M	
SGS-DRG-00A-S004	55	F	*
SGS-DRG-00A-S005	45	F	
SGS-DRG-00A-S006	41	M	
SGS-DRG-00A-S007	51	M	*

CORE-ID	Message	Dataset	USUBJID	Record	Variable(s)	Value(s)
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S001	1	AGE, SEX	42.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S014	7	AGE, SEX	42.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S024	9	AGE, SEX	48.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S033	13	AGE, SEX	45.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S034	14	AGE, SEX	55.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S039	16	AGE, SEX	41.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S047	19	AGE, SEX	48.0, F
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S048	20	AGE, SEX	44.0, M
ROMAN-0002	AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and SEX is equal to "F".	DM	SGS-DRG-001-01-S049	21	AGE, SEX	43.0, M
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Use Cases – custom CDISC Open Rules

Validate external data based on a non-SDTM define.xml

SGS

Use case: define.xml

Validate external data based on a non-SDTM define.xml

- Structure
- Codelist

LB (Labo) - [VENDOR 1.0] Location: labo.xpt

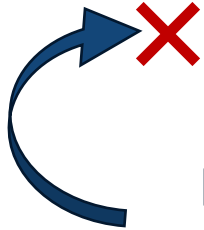
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
Trial_id	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
Site_id	Site identifier	text	Identifier	2		Assigned (Source: Sponsor)
Screenid	Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
Testname	Lab Test Name	text	Topic	6	Labo Test Code • "PROTEIN" = "Protein" • "MAGNESIUM" = "Magnesium" • "CALCIUM" = "Calcium"	Assigned (Source: Sponsor)
Gender	Gender	integer	Identifier	3		Derived (Source: Sponsor) [unresolved: MT.SEQ]
value	Result	text	Topic	6		Assigned (Source: Sponsor)
Units	Units	text	Topic	6		Assigned (Source: Sponsor)

Trial_id	Site_id	Country	Screenid	Testname	Gender	value	Unit
Study Identifier	*Site identifier*	*Country*	*Subject Identifier*	*Lab Test Name*	*Gender*	*value of the test*	*Original Units*
Char	*Char*	*char*	*Char*	*Char*	*Char*	*Char*	*Char*
50	*50*	*50*	*50*	*50*	*50*	*50*	*50*
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S001	PROTEINE	F	4.6	g/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S002	PROTEIN	F	73	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S003	PROTEINS	M	8	
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S004	CALCIUM	F	9.7	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S005	Magnesium	F	162	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S006	MAGNESIUM	F	23	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S007	GLUCOSE	M	77	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S008	MAGNESIUM	F	188	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S009	MAGNESIUM	F	2.1	
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S010	PHOSPHATE	M	4.4	mg/dL
SGS-DRG-001	L003	BE	SGS-DRG-001-01-S011	PROTEIN	F	7.7	g/dL
SGS-DRG-001	L004	BE	SGS-DRG-001-01-S012	ALT	M	16	U/L

Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Structure**
- Codelist



LB (Labo) - [VENDOR 1.0] Location: labo.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
Trial_id	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
Site_id	Site identifier	text	Identifier	2		Assigned (Source: Sponsor)
Screenid	Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
Testname	Lab Test Name	text	Topic	6	Labo Test Code • "PROTEIN" = "Protein" • "MAGNESIUM" = "Magnesium" • "CALCIUM" = "Calcium"	Assigned (Source: Sponsor)
Gender	Gender	integer	Identifier	3		Derived (Source: Sponsor) [unresolved: MT.SEQ]
value	Result	text	Topic	6		Assigned (Source: Sponsor)
Units	Units	text	Topic	6		Assigned (Source: Sponsor)

Trial_id	Site_id	Country	Screenid	Testname	Gender	value	Unit
Study Identifier	*Site identifier*	*Country*	*Subject Identifier*	*Lab Test Name*	*Gender*	*value of the test*	*Original Units*
Char	*Char*	*char*	*Char*	*Char*	*Char*	*Char*	*Char*
50	*50*	*50*	*50*	*50*	*50*	*50*	*50*
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S001	PROTEINE	F	4.6	g/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S002	PROTEIN	F	73	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S003	PROTEINS	M	8	
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S004	CALCIUM	F	9.7	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S005	Magnesium	F	162	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S006	MAGNESIUM	F	23	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S007	GLUCOSE	M	77	mg/dL
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S008	MAGNESIUM	F	188	U/L
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S009	MAGNESIUM	F	2.1	
SGS-DRG-001	L001	BE	SGS-DRG-001-01-S010	PHOSPHATE	M	4.4	mg/dL
SGS-DRG-001	L003	BE	SGS-DRG-001-01-S011	PROTEIN	F	7.7	g/dL
SGS-DRG-001	L004	BE	SGS-DRG-001-01-S012	ALT	M	16	U/L

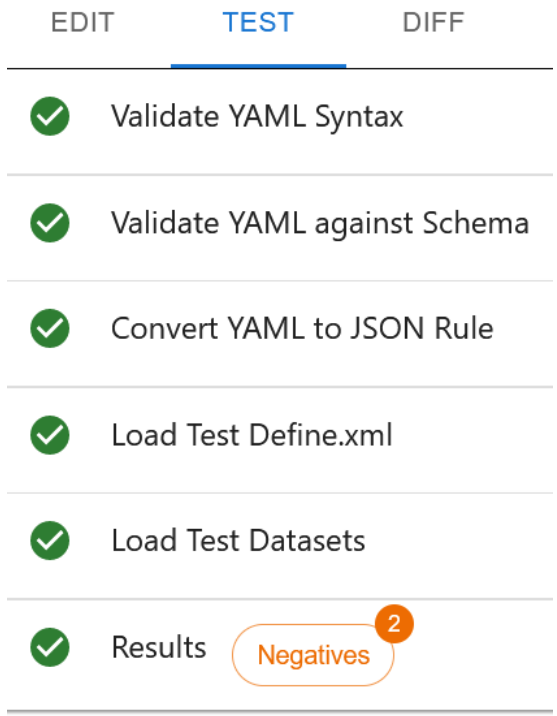
Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Structure**

```yaml
Check:
  all:
    - name: variable_name
      operator: not_equal_to
      value: define_variable_name
Core:
  Id: "ROM-004"
  Status: Draft
  Version: '1'
Description: 'Raise an error when the variable name
in the define.xml does not
  correspond to the variable name in the dataset'
Executability: Fully Executable
Outcome:
  Message: Variable in dataset not available in the
  define.xml
Rule Type: Variable Metadata Check against Define XML
```

Rule Editor



Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Structure**


```
{ 1 item
  "LB" : [ 1 item
    0 : { 5 items
      "executionStatus" : "success"
      "domain" : "LB"
      "variables" : [ 1 item
        0 : "variable_name"
      ]
      "message" : "Variable in dataset not available in the define.xml"
      "errors" : [ 2 items
        0 : { 2 items
          "value" : { 1 item
            "variable_name" : "Country"
          }
          "row" : 3
        }
        1 : { 2 items
          "value" : { 1 item
            "variable_name" : "Unit"
          }
          "row" : 8
        }
      ]
    }
  ]
}
```

Use case: define.xml

Validate external data based on a non-SDTM define.xml

- Structure
- **Codelist**

LB (Labo) - [VENDOR 1.0] Location: labo.xpt

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
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Screenid	Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
Testname	Lab Test Name	text	Topic	6	Labo Test Code • "PROTEIN" = "Protein" • "MAGNESIUM" = "Magnesium" • "CALCIUM" = "Calcium"	Assigned (Source: Sponsor)
Gender	Gender	integer	Identifier			Derived (Source: Sponsor) [unresolved: MT.SEQ]
value	Result	text	Topic	6		Assigned (Source: Sponsor)
Units	Units	text	Topic	6		Assigned (Source: Sponsor)

Trial_id	Site_id	Screenid	Testname	Gender	value	Units
Study Identifier	*Site identifier*	*Subject Identifier*	*Lab Test Name*	*Gender*	*value of the test*	*Original Units*
Char	*Char*	*Char*	*Char*	*Char*	*Char*	*Char*
50	*50*	*50*	*50*	*50*	*50*	*50*
SGS-DRG-001	L001	SGS-DRG-001-01-S001	PROTEINE	F	4.6	g/dL
SGS-DRG-001	L001	SGS-DRG-001-01-S002	PROTEIN	F	73	U/L
SGS-DRG-001	L001	SGS-DRG-001-01-S003	PROTEINS	M	8	
SGS-DRG-001	L001	SGS-DRG-001-01-S004	CALCIUM	F	9.7	mg/dL
SGS-DRG-001	L001	SGS-DRG-001-01-S005	Magnesium	F	162	mg/dL
SGS-DRG-001	L001	SGS-DRG-001-01-S006	MAGNESIUM	F	23	U/L
SGS-DRG-001	L001	SGS-DRG-001-01-S007	GLUCOSE	M	77	mg/dL
SGS-DRG-001	L001	SGS-DRG-001-01-S008	MAGNESIUM	F	188	U/L
SGS-DRG-001	L001	SGS-DRG-001-01-S009	MAGNESIUM	F	2.1	
SGS-DRG-001	L001	SGS-DRG-001-01-S010	PHOSPHATE	M	4.4	mg/dL
SGS-DRG-001	L003	SGS-DRG-001-01-S011	PROTEIN	F	7.7	g/dL
SGS-DRG-001	L004	SGS-DRG-001-01-S012	ALT	M	16	U/L

Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Codelist**

```yaml
Check:
  all:
    - name: define_variable_ccode
      operator: non_empty
    - name: variable_value
      operator: non_empty
    - name: define_variable_has_codelist
      operator: equal_to
      value: true
    - name: variable_value
      operator: is_not_contained_by
      value: define_variable_codelist_coded_values
```

Rule Editor

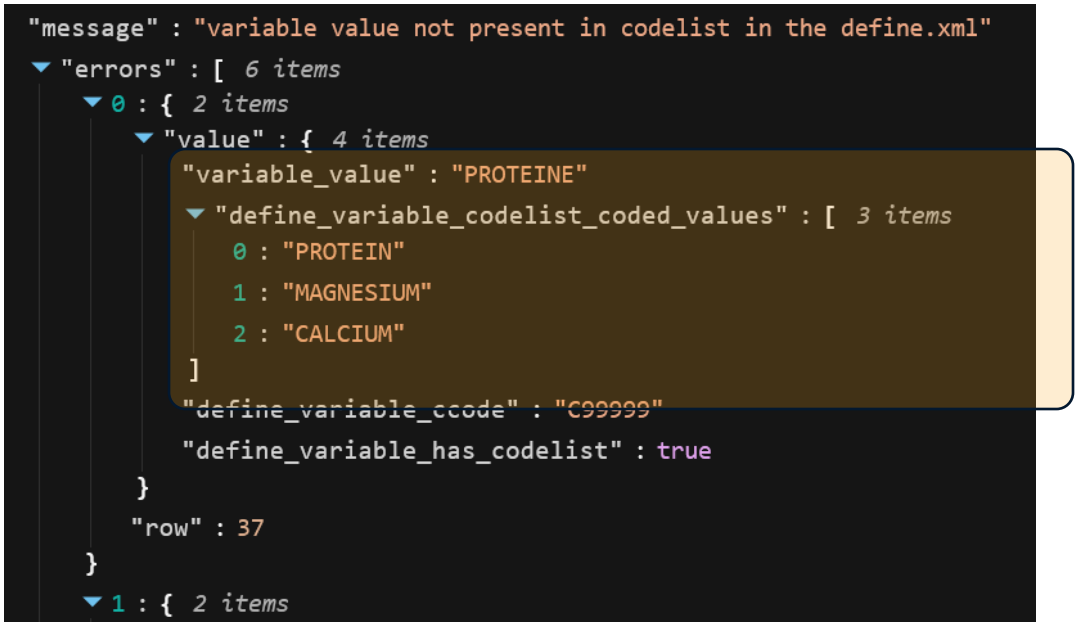
EDIT | TEST | DIFF

- Validate YAML Syntax
- Validate YAML against Schema
- Convert YAML to JSON Rule
- Load Test Define.xml
- Load Test Datasets
- Results — Negatives 6

Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Codelist**



Use case: define.xml

Validate external data based on a non-SDTM define.xml

- **Structure** ✓
- **Codelist** ✓

- Data types, value length, label, value lists, …

- Rules are neither trial, vendor, transfer nor standard specific and could therefore potentially be used for any vendor transfer

- Enormous potential
  - Data transfer agreement between sponsor/CRO/Vendor → define.xml
    - Automate validation of the transfers
  - Annotate vendor define.xml to SDTM
    - Automate the SDTM creation

cdisc

SGS

Suggestions for CDISC Open Rules

Suggestions for CDISC Open Rules

- Good rule governance
  - User / roles
  - Categorisation
- Follow-up on the output
  - Producing excel/JSON
- AI integration in the editor

EDIT TEST DIFF

Hello there! My name is COR-E, which rule do you want me to create today?

Hi COR-E, can you please create a rule that checks if a subject has taken more than 250 mg of Paracetamol?

Certainly! Here's the requested rule. Do you want me to create test data for it?

Yes, that would be very helpful

Sure, no problem, here you go!

testData.xlsx

All 7 rules loaded.

```
Authorities:
  - Organizatio
    Standards:
      - Name: S
        Version
        eferen
          - Origin: SDTMIG Conformance Rules
            Rule Identifier:
              Id: CGXXXX
            Criteria:
              Type: Failure
            Version: 2.0

Core:
  Id: CORE-000001
  Version: 1
  Status: Draft

Description: >
  This rule checks that no subject has taken more than

Rule Type: Record Data

Scope:
  Classes:
    Include:
      - INTERVENTIONS
  Domains:
```

RO

CDISC CORE Rule Generator

By Roman Radelicki

Generates CDISC CORE rules in YAML code format.

Generate a CDISC CORE rule for LB domain and creat...

Create a YAML rule for the DM domain and provide test...

Generate test data for a new rule in the AE domain.

Provide YAML code and test data for a rule in the VS...

Message CDISC CORE Rule Generator

SGS

The YAML rule has been created, and the test data for the CM dataset has been generated and saved in an Excel file. You can download the test data from the following link:

CM_Test_Data.xlsx

This test data includes records that trigger the rule and records that do not, providing a comprehensive set for validation.

Thank You!

Contact us

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