



SGS Health Science

CORE: Authoring & Running Your Own Rules

Health Inspired, Quality Driven.

Roman Radelicki, Head Data Technology, June 2024



Disclaimer and disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC and/or SGS.*
- *The author(s) have no real or apparent conflicts of interest to report.*

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- Member of the CDISC CORE community group
- Consultancy regarding CDISC CORE
- CDISC authorized instructor



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- Expert guidance for your CDISC CORE projects
- Learn from a CDISC authorized instructor

Talk to us!

clinicalresearch@sgs.com

Agenda



- 01 About CDISC CORE
- 02 How develop CORE rules
- 03 Custom CORE rules
- 04 Who can create CORE rules
- 05 Creating custom CORE rules
- 06 Use cases
- 07 Suggestions
- 08 Key takeaways
- 09 Q&A

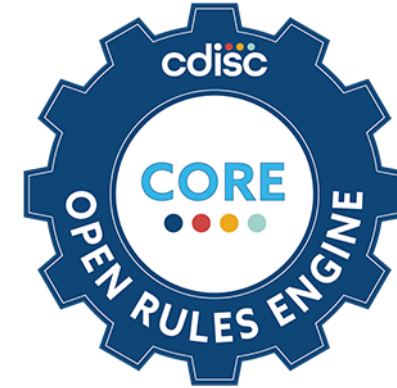


01 About CDISC CORE

About CDISC CORE

Rules

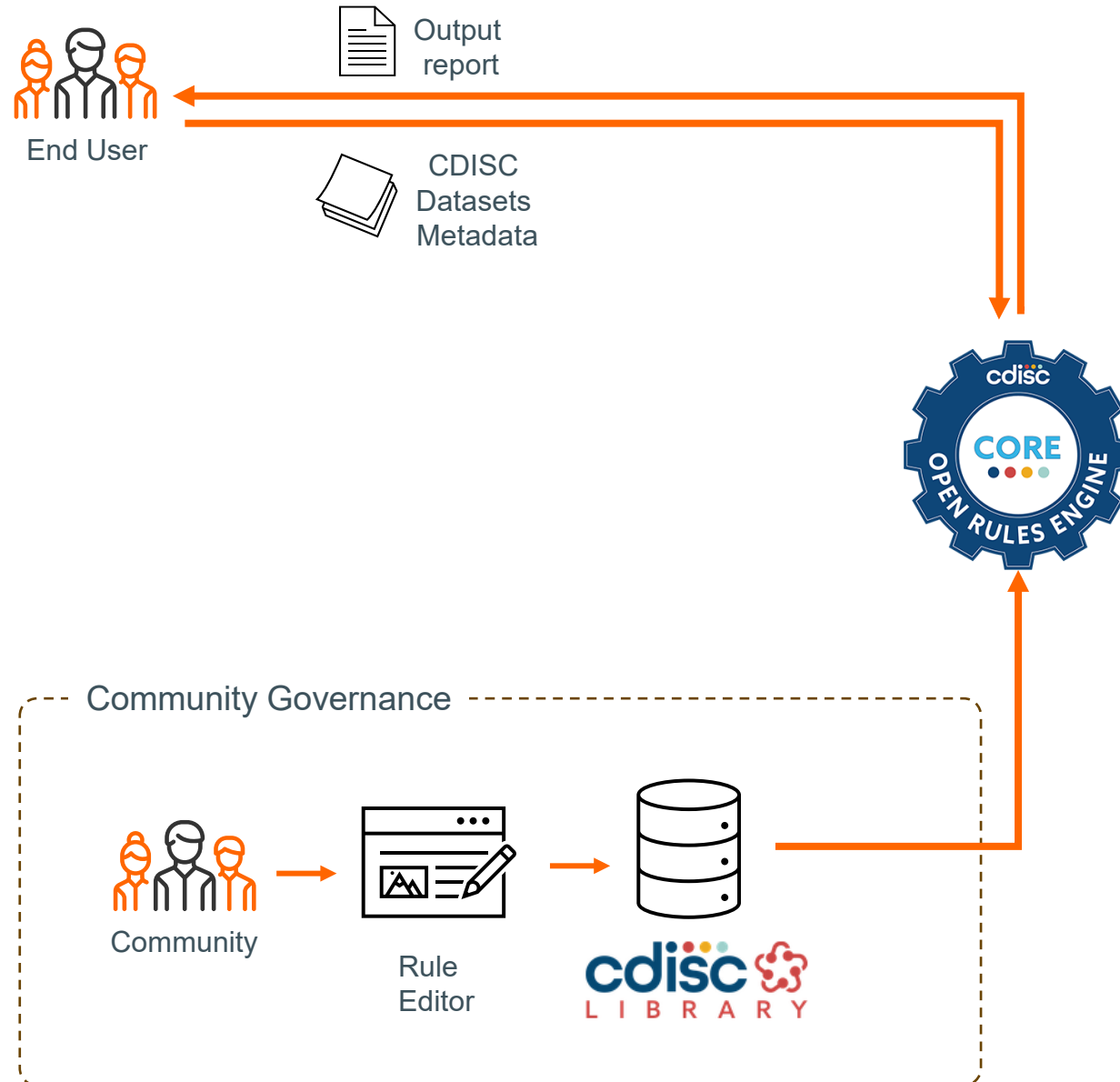
- CDISC governed – single source of truth
- Community driven
- Executable rules
- Submission ready
- Open-Source





02 How can we develop rules with CDISC CORE?

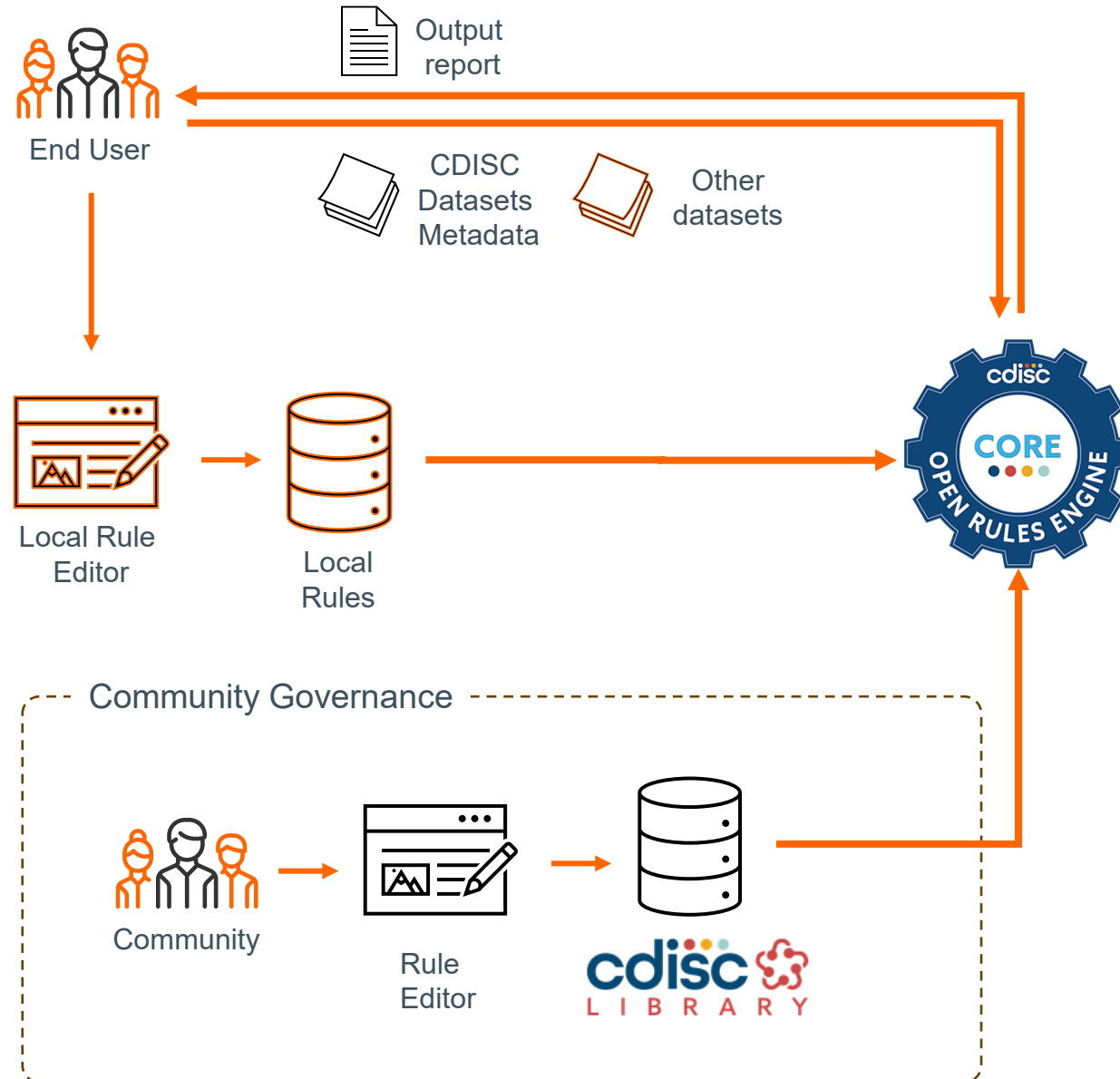
Developing rules with CDISC CORE





03 Can we create our own rules in CDISC CORE?

Developing own rules with CDISC CORE

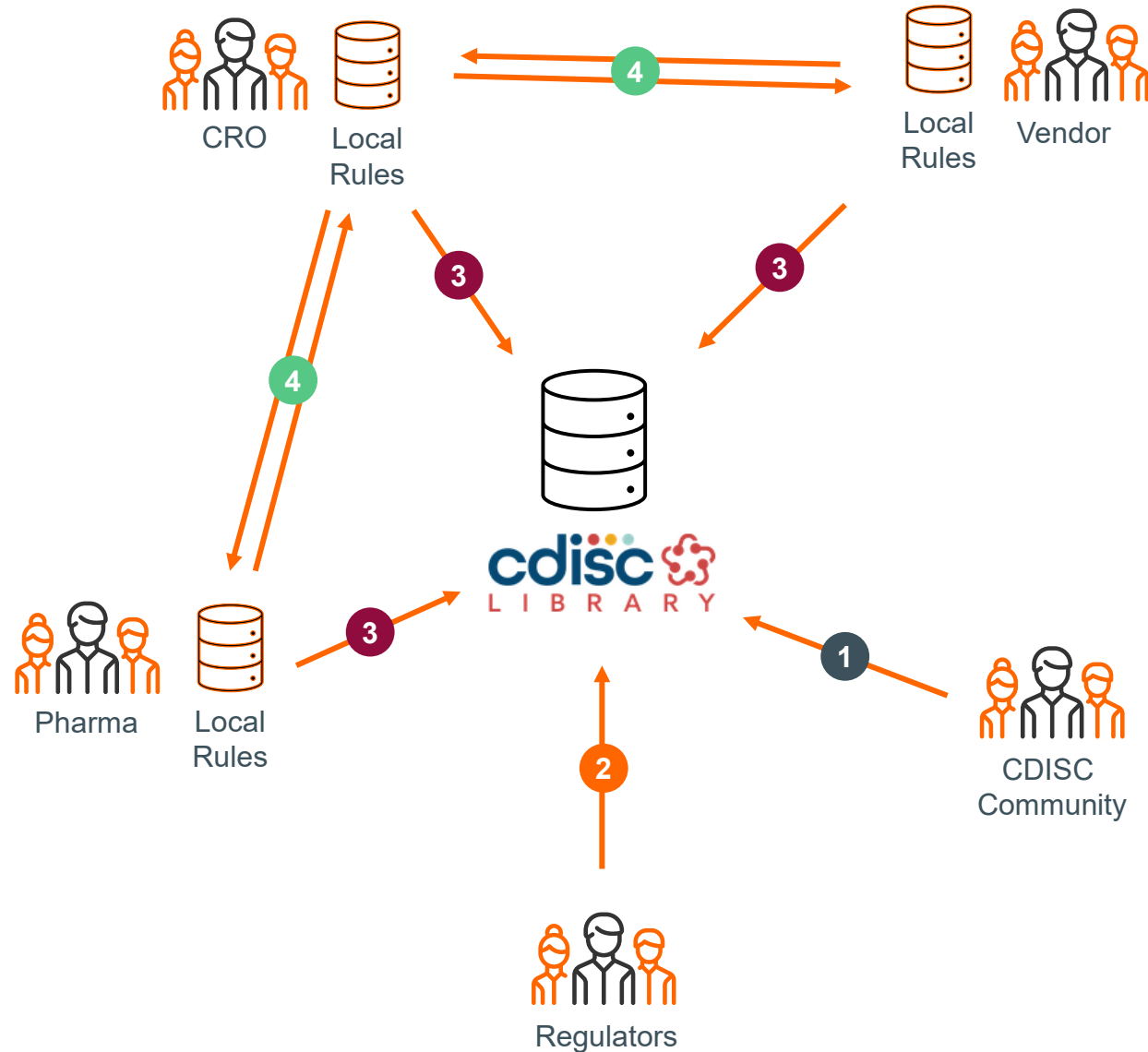




04 Who can create rules in CDISC CORE and why should we?

Who can create CORE rules

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



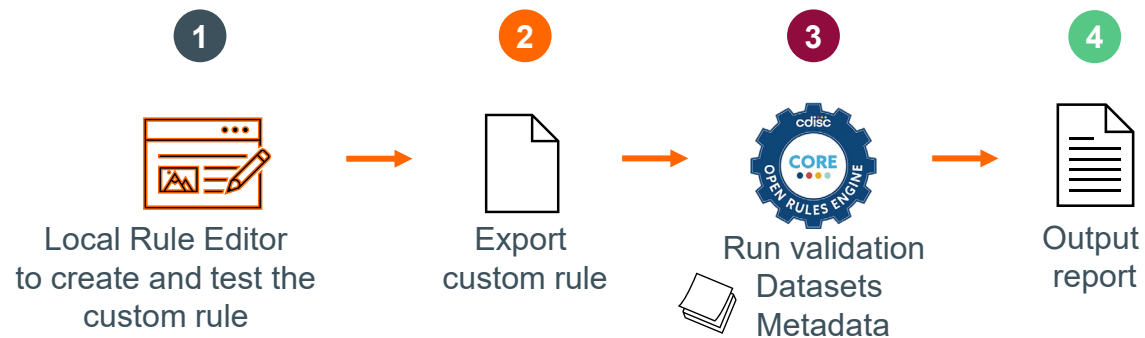


05 How to create custom CORE rules?

Creating custom CORE rules

Process flow:

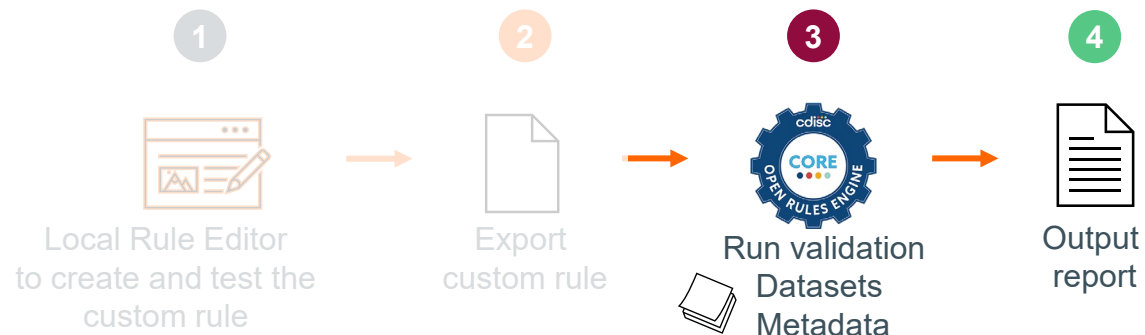
- Rule Editor
 - 1 Create and test the rule
 - 2 Export rule
- Rules Engine
 - 3 Run validation with the custom rule
 - 4 Output report



Creating custom CORE rules

Process flow:

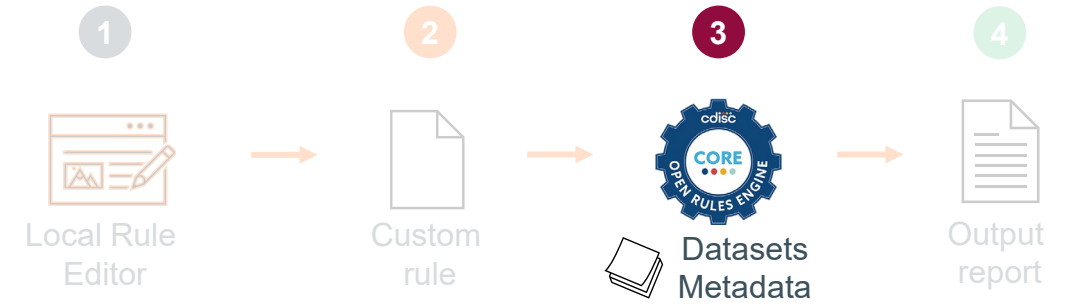
- Rule Editor
 - 1 Create and test the rule
 - 2 Export rule
- Rules Engine
 - 3 Run validation with the custom rule
 - 4 Output report



Creating custom CORE rules

Rules Engine

- Command line interface – or source code
- Can be incorporated into existing tooling or run as a standalone application
- Latest releases can be downloaded from the GitHub release page:
<https://github.com/cdisc-org/cdisc-rules-engine/releases>



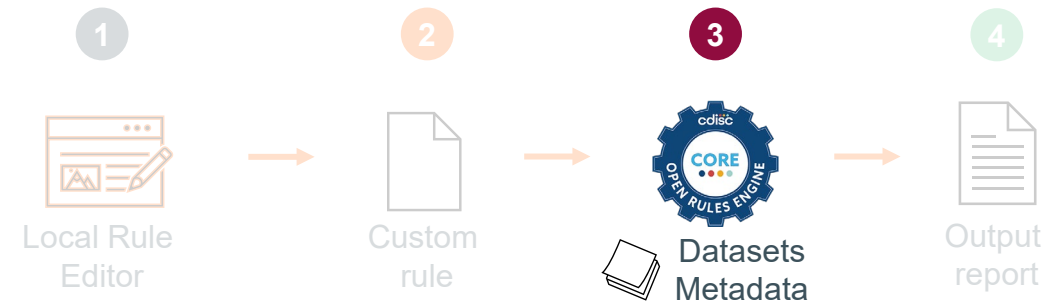
Creating custom CORE rules

Rules Engine

- Zip file
- Example:

Open Command prompt and navigate to the core folder and use following basic command to perform a validation

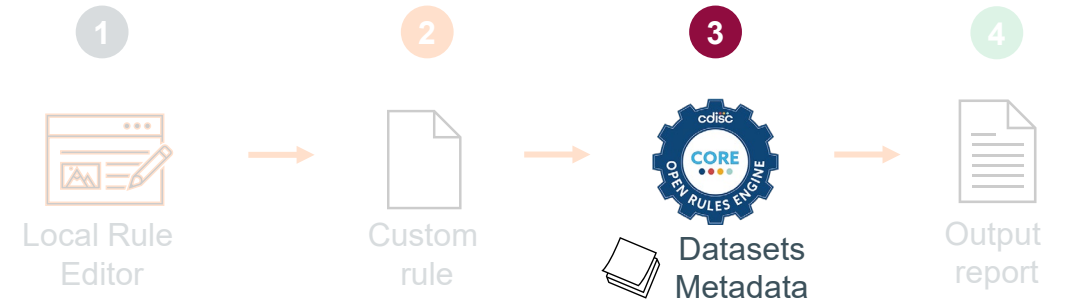
- `.\core validate -s <standard> -v <standard version> -d path/to/datasets`
- `core validate -s sdtmig -v 3-4 -d c:\core_data\data\`



Creating custom CORE rules

Rules Engine commands:

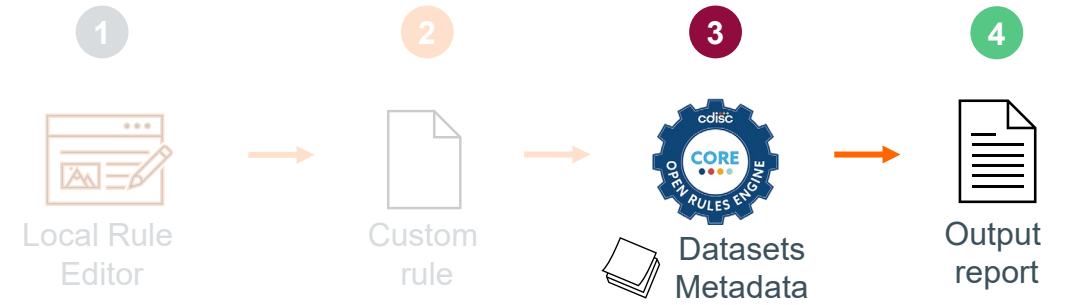
- -dvp: path to the define.xml
- -ct: Controlled terminology package to validate against
- -o: location where the output reports is stored
- -of: output format [JSON|XLSX]
- -whodrug: location of the WHODrug dictionary
- -meddra: location of the MedDRA dictionary
- -r: to run only 1 or multiple specific rules
- **-lr: local rules: path to local rules in yml or json format**
- ...



Creating custom CORE rules

Rules Engine:

- Command line interface – or source code
 - Easy to integrate in already existing process flows
 - Nightly automatic conversion workflow
- CLI – UI interface for less tech-savvy people
 - Proof of concept



Custom CORE rules - Engine

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

SGS CORE Validator

Standard:

Version:

Define Version:

Dataset Selection: xpt json path

Dataset Files:

Define XML:

CT Packages:

WHODrug Directory:

MedDRA Directory:

Rules:

Local Rules:

Report Format: xlsx json

Report Location:

Log Level: disabled critical error warn info debug

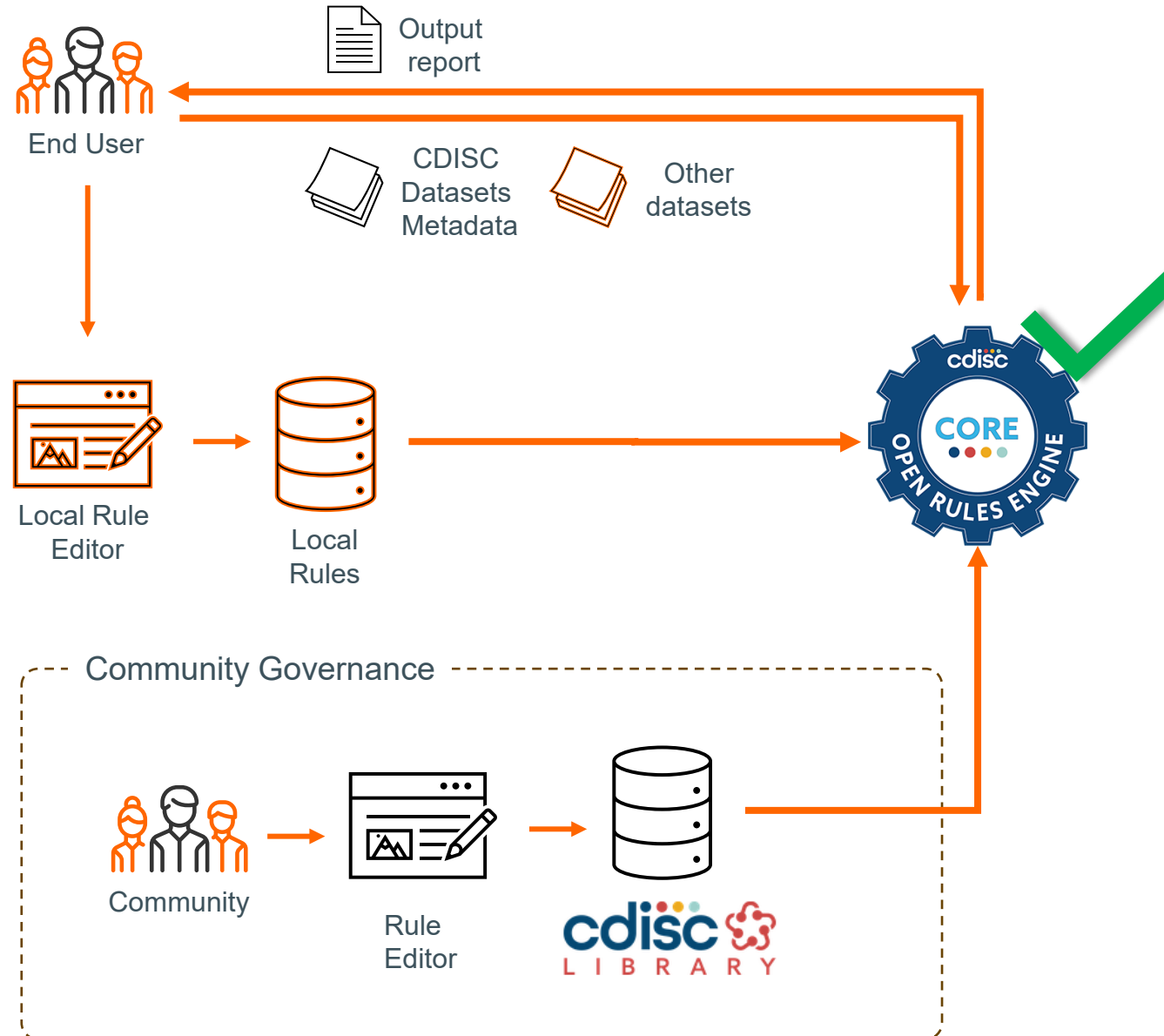
Log Location:

Location Rules Engine:

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

Process is running...

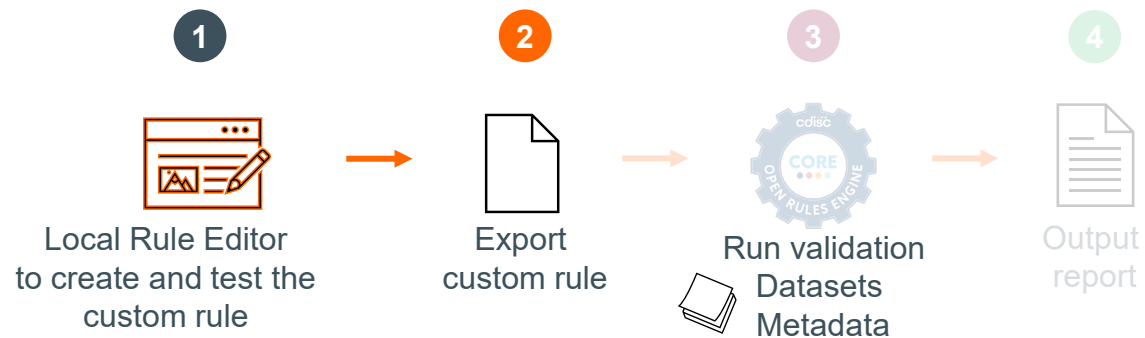
Creating custom CORE rules



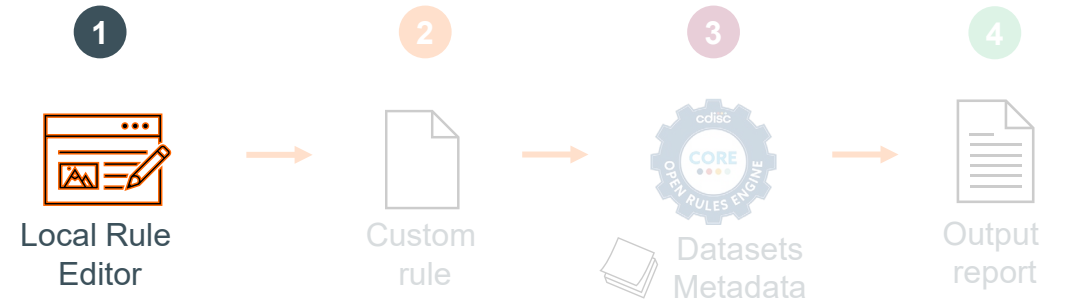
Creating custom CORE rules

Process flow:

- Rule Editor
 - 1 Create and test the rule
 - 2 Export rule
- Rules Engine
 - 3 Run validation with the custom rule
 - 4 Output report



Creating custom CORE rules



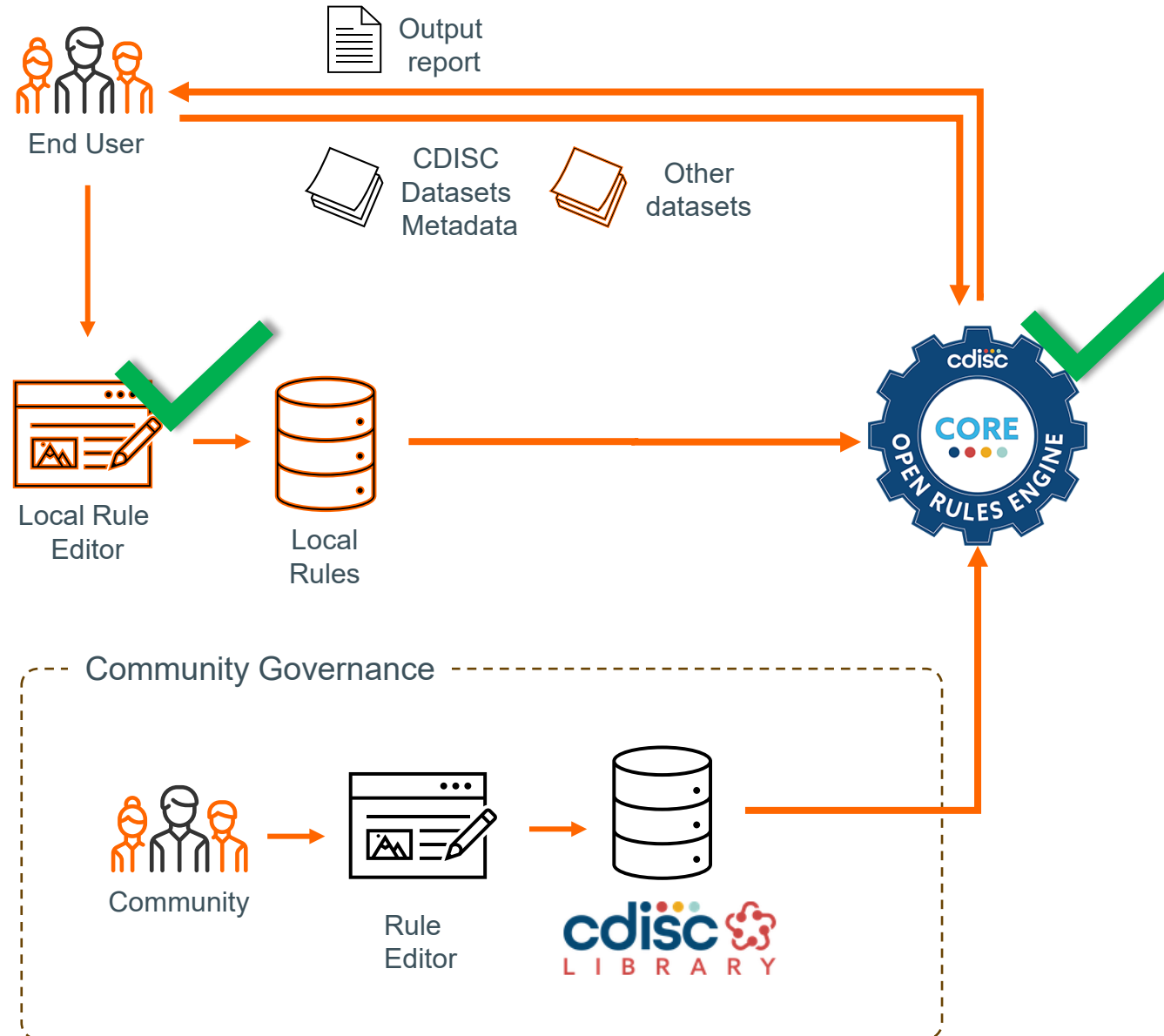
Rule Editor:

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

Rule Ids	Creator
CG0176	Radelicki, Roman (Mechelen)

```
1 Authorities:
2   - Organization: CDISC
3   Standards:
4     - Name: SDTMIG
5     References:
6       - Citations:
7         - Cited Guidance: The intent of the
8           domain model is to collect
9             responses to only
10              those criteria that the subject
11                did not meet, and not the
12                  responses to all criteria.
13              Document: SDTM v3.4
14              Section: 6.3.4
15              Origin: SDTM and SDTMIG Conformance
16                Rules
17              Rule Identifier:
18                Id: CG0176
19                Version: '1'
20                Version: '2.0'
21              Version: '3.4'
22     - Name: SDTMIG
23     References:
24       - Citations:
25         - Cited Guidance: The intent of the
26           domain model is to collect response
```


Creating custom CORE rules





06 Use cases – custom CDISC CORE rule

Case #1

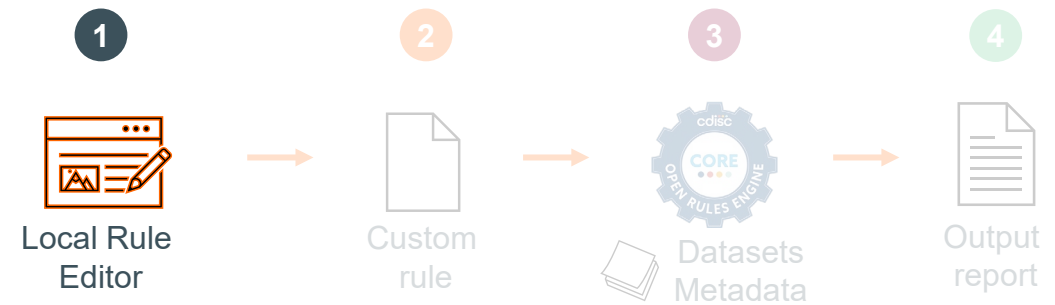


Challenge:

Is it possible to create a custom rule not currently included in the CDISC-governed set?

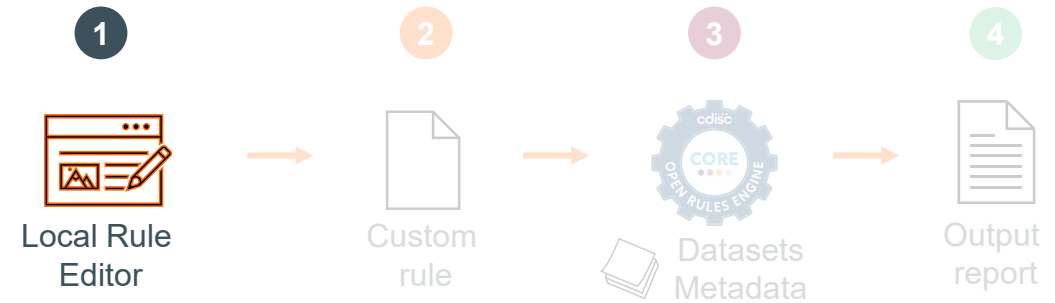
Case #1

- Rule not currently included in the CDISC-governed set
 - Check that when the reference range indicator (--NRIND) is completed that a result is completed (--ORRES or --STRESC or --STRESN)



```
48 Check:
49   all:
50     - name: --NRIND
51       operator: non_empty
52     - name: --ORRES
53       operator: empty
54     - name: --STRESC
55       operator: empty
56     - name: --STRESN
57       operator: empty
58 Core:
59   Id: ROMAN-0001
60   Status: Draft
61   Version: '1'
62   Description: Verify that --ORRES or --STRESC or --STRESN is
63   not empty when
64   --NRIND is completed
65   Executability: Fully Executable
66   Outcome:
67     Message: --ORRES or --STRESC or --STRESN should be completed
68     when --NRIND is completed
69   Rule Type: Record Data
70   Scope:
71     Classes:
72       Include:
73         - FINDINGS
74     Domains:
75       Include:
76         - ALL
77   Sensitivity: Record
```

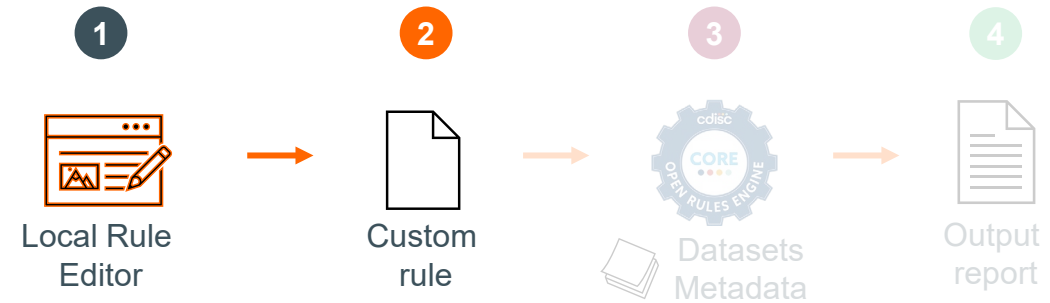
Case #1



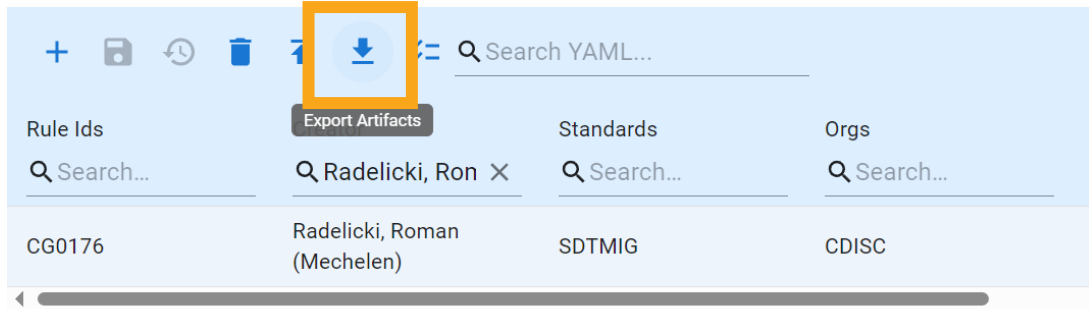
```
Check:
  all:
    - name: --NRIND
      operator: non_empty
    - name: --ORRES
      operator: empty
    - name: --STRESC
      operator: empty
    - name: --STRESN
      operator: empty
```

```
48 Check:
49   all:
50     - name: --NRIND
51       operator: non_empty
52     - name: --ORRES
53       operator: empty
54     - name: --STRESC
55       operator: empty
56     - name: --STRESN
57       operator: empty
58 Core:
59   Id: ROMAN-0001
60   Status: Draft
61   Version: '1'
62 Description: Verify that --ORRES or --STRESC or --STRESN is
63 not empty when
64   --NRIND is completed
64 Executability: Fully Executable
65 Outcome:
66   Message: --ORRES or --STRESC or --STRESN should be completed
67   when --NRIND is completed
67 Rule Type: Record Data
68 Scope:
69   Classes:
70     Include:
71     - FINDINGS
72   Domains:
73     Include:
74     - ALL
75 Sensitivity: Record
```

Case #1



Export the rule in YAML format

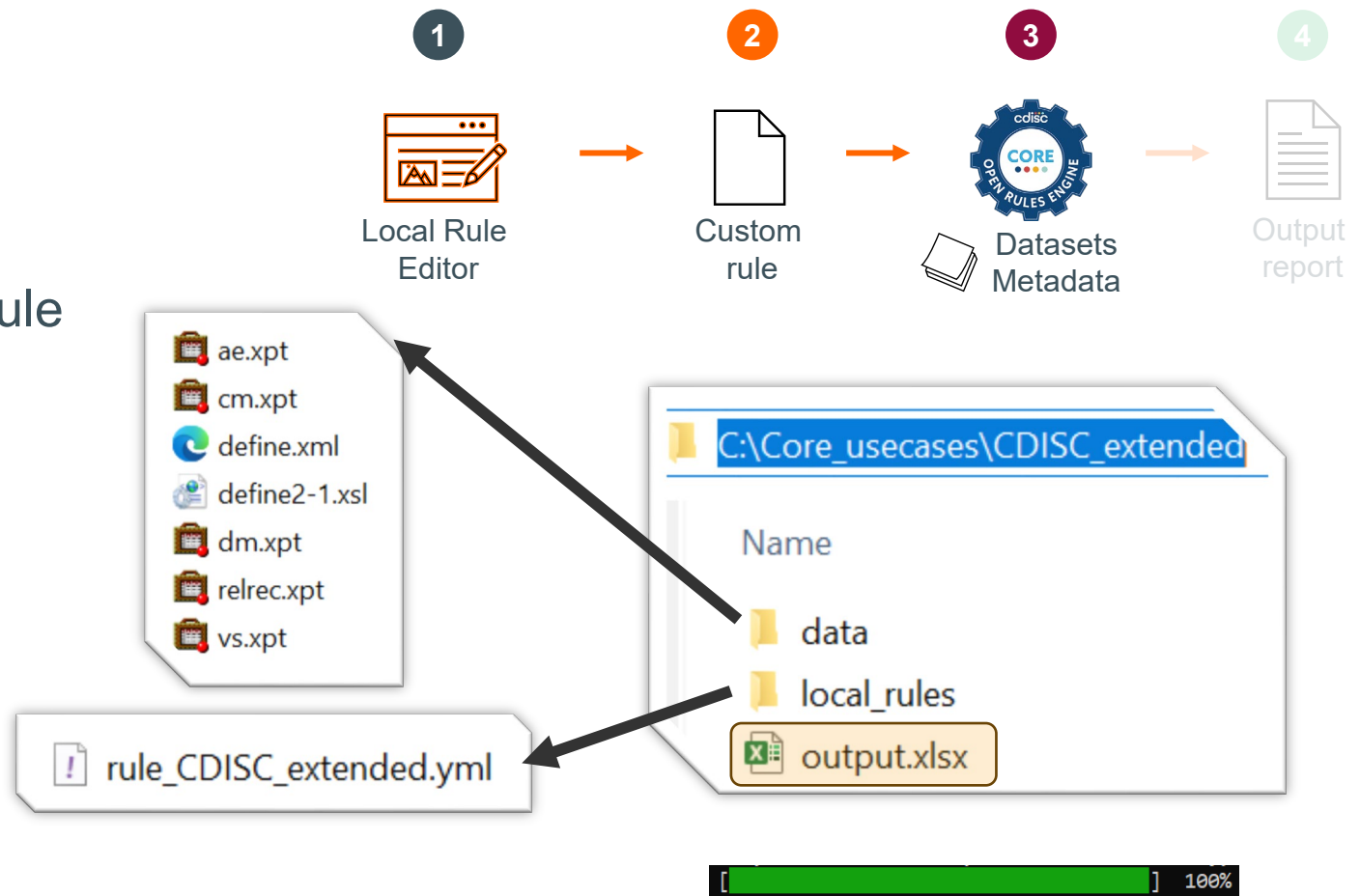


All 1 rules loaded.

```
48 Check:
49   all:
50     - name: --NRIND
51       operator: non_empty
52     - name: --ORRES
53       operator: empty
54     - name: --STRESC
55       operator: empty
56     - name: --STRESN
57       operator: empty
58 Core:
59   Id: ROMAN-0001
60   Status: Draft
61   Version: '1'
62 Description: Verify that --ORRES or --STRESC or --STRESN is
63 not empty when
64 --NRIND is completed
65 Executability: Fully Executable
66 Outcome:
67   Message: --ORRES or --STRESC or --STRESN should be completed
68   when --NRIND is completed
69 Rule Type: Record Data
70 Scope:
71   Classes:
72     Include:
73     - FINDINGS
74   Domains:
75     Include:
76     - ALL
77 Sensitivity: Record
```

Case #1

- Run a validation with this local custom rule



- core validate

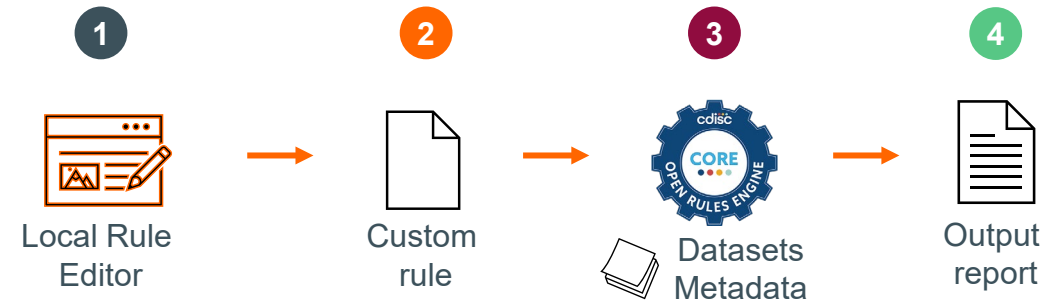
```
-lr C:\Core_usecases\CDISC_extended\local_rules
```

```
-s sdtmig -v 3-4
```

```
-d C:\Core_usecases\CDISC_extended\data
```

```
-o C:\Core_usecases\CDISC_extended\output
```

Case #1



Conformance Details					Dataset Details		Issue Summary		Issue Details		Rules Report (+)	
CORE-ID	Version	CDISC RuleID	Message						Status			
ROMAN-0001	1	CG0176	--ORRES or --STRESC or --STRESN should be completed when --NRIND is completed						SUCCESS			

Conformance Details		Dataset Details		Issue Summary		Issue Details		Rules Report (+)	
Dataset	CORE-ID	Message				Issues			
VS	ROMAN-0001	VSORRES or VSSTRESC or VSSTRESN should be completed when VSNRIND is completed				2			

Conformance Details		Dataset Details		Issue Summary		Issue Details		Rules Report (+)	
CORE-ID	Message	Dataset	USUBJID	Record	Sequence	Variable(s)	Value(s)		
ROMAN-0001	VSORRES or VSSTRESC or VSSTRESN should be completed when VSNRIND is completed	VS	SGS-DRG-001-01-S001	10	10	VSNRIND, VSORRES, VSSTRESC, VSSTRESN	NORMAL, None, None, None		
ROMAN-0001	VSORRES or VSSTRESC or VSSTRESN should be completed when VSNRIND is completed	VS	SGS-DRG-001-01-S001	28	28	VSNRIND, VSORRES, VSSTRESC, VSSTRESN	NORMAL, None, None, None		

Case #1



Challenge:

Is it possible to create a custom rule not currently included in the CDISC-governed set?



Case #2



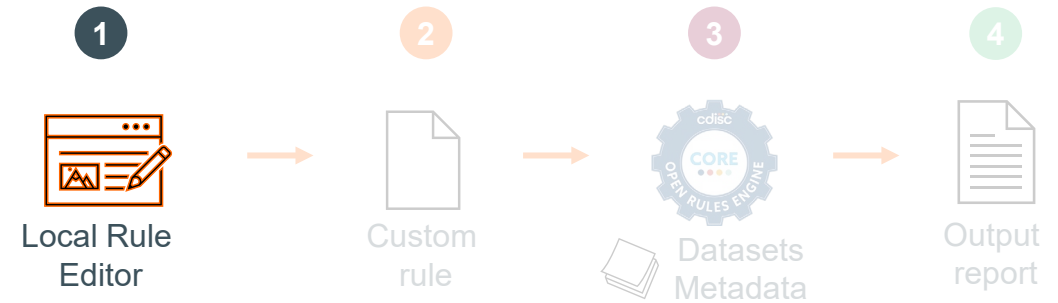
Challenge:

Is it possible to create a custom rule for data cleaning?

Case #2

- Data cleaning rule

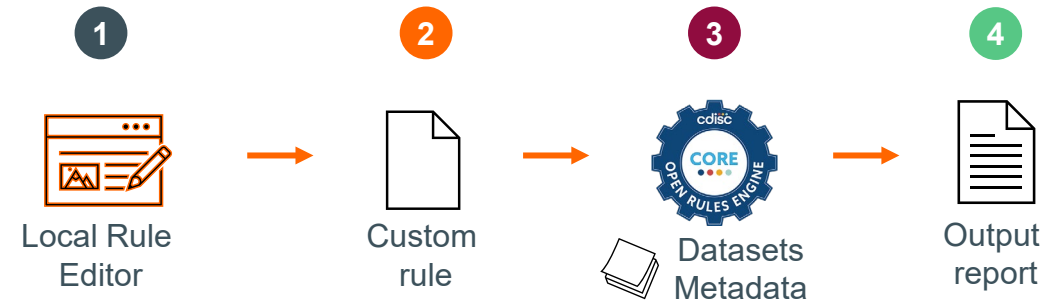
- in Accordance with the in/exclusion criteria, raise an error for male subjects older than 40 and female subjects older than 41



```
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
```

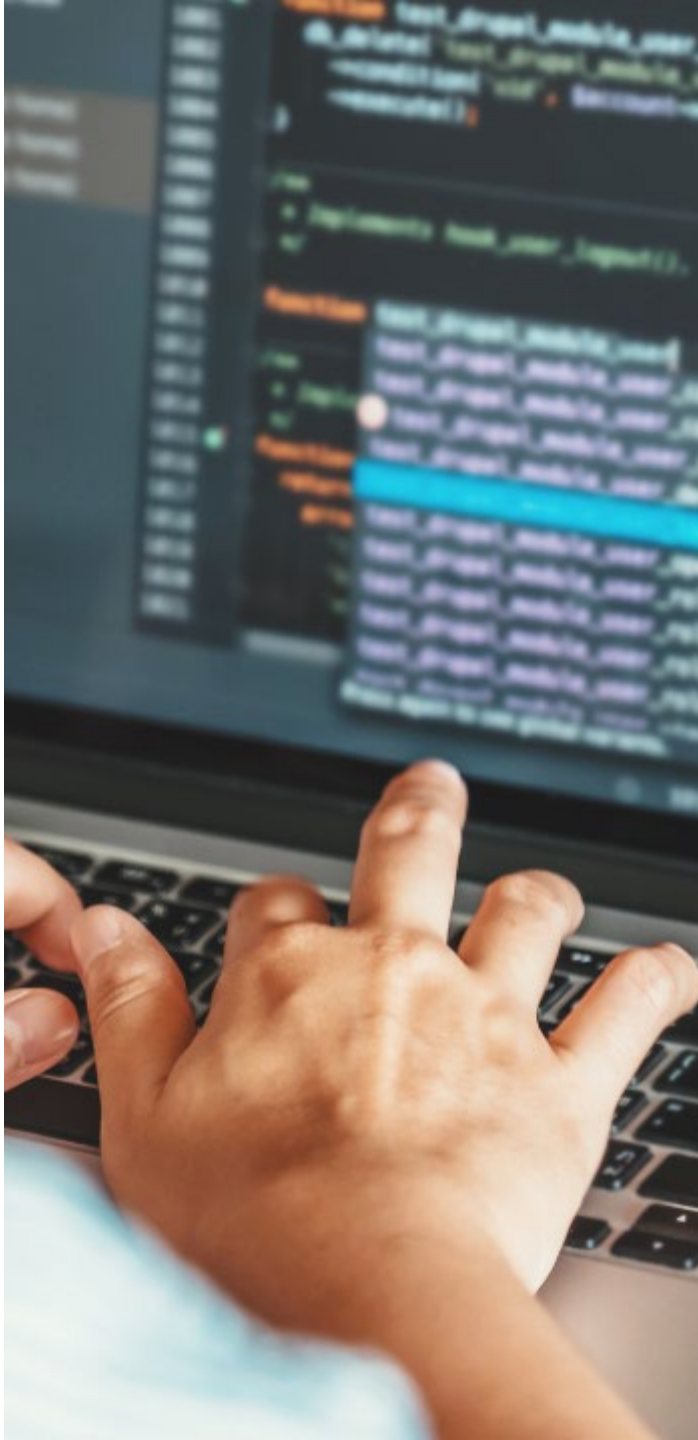
```
48 ✓ Check:
49   any:
50     - all:
51       - name: AGE
52         operator: greater_than
53         value: 40
54       - name: SEX
55         operator: equal_to
56         value: M
57     - all:
58       - name: AGE
59         operator: greater_than
60         value: 41
61       - name: SEX
62         operator: equal_to
63         value: F
64 ✓ Core:
65   Id: "ROMAN-0002"
66   Status: Draft
67   Version: '1'
68   Description: in Accordance to the inclusion/exclusion criteria, Raise an error if
69     the male subject's age is greater than 40 and the female subject's age is greater
70     than 41.
69   Executability: Fully Executable
70 ✓ Outcome:
71   Message: AGE greater than 40 and SEX is equal to "M" or AGE greater than 41 and
72     SEX is equal to "F".
72   Rule Type: Record Data
73 ✓ Scope:
74   Classes:
75     Include:
76       - SPECIAL PURPOSE
77   Domains:
78     Include:
79       - DM
80   Sensitivity: Record
```

Case #2



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

Case #2



Challenge:

Is it possible to create a custom rule for data cleaning?



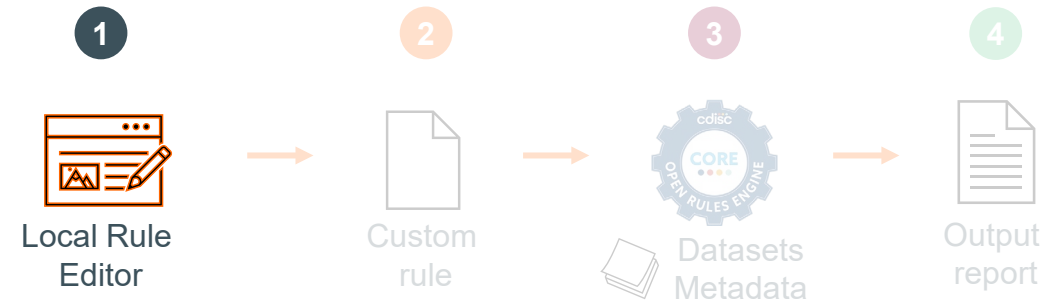
Case #3



Challenge:

Is it possible to create a custom rule for non-CDISC clinical data such as external vendor data?

Case #3



- non-CDISC clinical data such as external vendor data
 - Raise an error when there is no unit but test name and value are completed

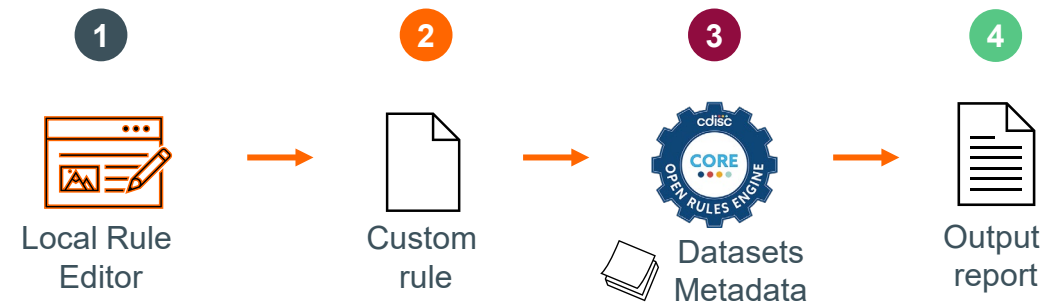
labo.xpt

	Trial_ID	Site_id	Screenid	testname	Gender	value	Units
1	SGS-DRG-001	L001	SGS-DRG-001-01-S001	PROTEIN	F	4.6	g/dL
2	SGS-DRG-001	L001	SGS-DRG-001-01-S002	PROTEIN	F	73	U/L
3	SGS-DRG-001	L001	SGS-DRG-001-01-S003	PROTEIN	M	8	
4	SGS-DRG-001	L001	SGS-DRG-001-01-S004	CALCIUM	F	9.7	mg/dL
5	SGS-DRG-001	L001	SGS-DRG-001-01-S005	MAGNESIUM	F	162	mg/dL
6	SGS-DRG-001	L001	SGS-DRG-001-01-S006	MAGNESIUM	F	23	U/L
7	SGS-DRG-001	L001	SGS-DRG-001-01-S007	GLUCOSE	M	77	mg/dL
8	SGS-DRG-001	L001	SGS-DRG-001-01-S008	MAGNESIUM	F	188	U/L
9	SGS-DRG-001	L001	SGS-DRG-001-01-S009	MAGNESIUM	F	2.1	
10	SGS-DRG-001	L001	SGS-DRG-001-01-S010	PHOSPHATE	M	4.4	mg/dL
11	SGS-DRG-001	L002	SGS-DRG-001-01-S011	PROTEIN	F	7.7	g/dL
12	SGS-DRG-001	L003	SGS-DRG-001-01-S012	ALT	M	16	U/L
13	SGS-DRG-001	L004	SGS-DRG-001-01-S013	ALT	M	18	U/L

```
Check:
all:
- name: testname
  operator: non_empty
- name: value
  operator: non_empty
- name: Units
  operator: empty
- name: Screenid
  operator: exists
```

Case #3

- non-CDISC clinical data such as external vendor data



CORE-ID	Version	CDISC RuleID	Message	Status
ROMAN-0003	1	CG0176	No result unit completed	SUCCESS

CORE-ID	Message	Dataset	USUBJID	Record	Sequence	Variable(s)	Value(s)
ROMAN-0003	No result unit completed	LABO		3		Screenid, Units, testname, value	SGS-DRG-001-01-S003, , PROTEIN, 8.0
ROMAN-0003	No result unit completed	LABO		9		Screenid, Units, testname, value	SGS-DRG-001-01-S009, , MAGNESIUM, 2.1

Case #3



Challenge:

Is it possible to create a custom rule for non-CDISC clinical data such as external vendor data?



Other use cases



Challenge: Data listings?

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

Eager to help you get started with CDISC CORE



Roman Radelicki

Head Data Technology at SGS



Marisa Wyckmans

Data Management System and
Process Manager at SGS



Els Janssens

Data Management System and
Process Manager at SGS

- Expert guidance for your CDISC CORE projects
- Learn from a CDISC authorized instructor

Talk to us!

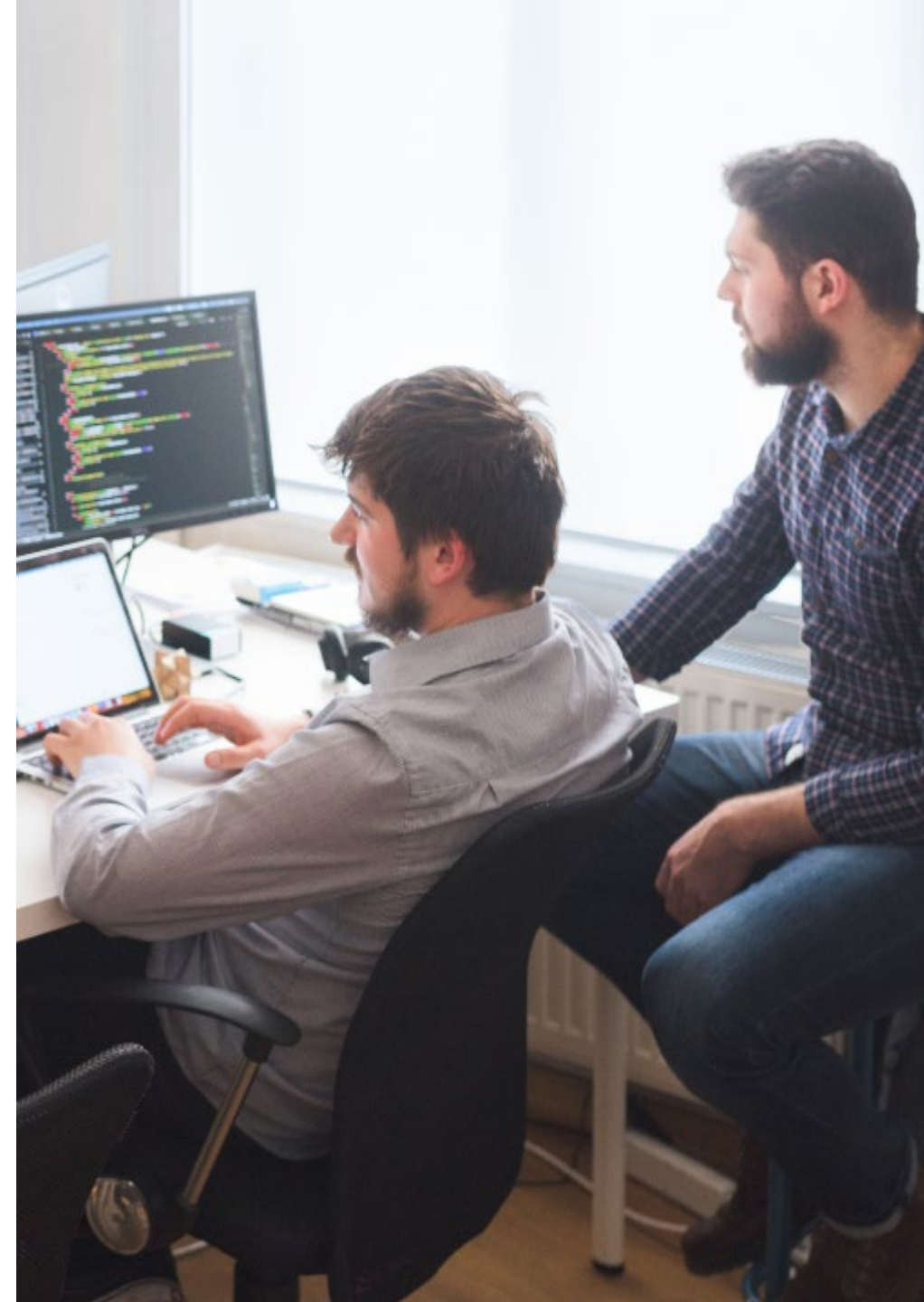
clinicalresearch@sgs.com



07 Suggestions for CDISC CORE

Suggestions to the CDISC CORE community

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



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:
- Organization:
Standards:
- Name: S
Version
Referen
- Origin: SDTMIG Conformance Rules
Rule Identifier:
  Id: CGXXX
Criteria:
  Type: Failure
  Version: 2.0

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

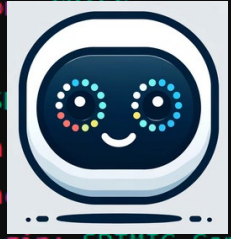
Description: >
  This rule checks that no subject has taken more than

Rule Type: Record Data

Scope:
  Classes:
  Include:
    - INTERVENTIONS

Domains:

```





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



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. [\[>-\]](#)



Message CDISC CORE Rule Generator





08 Key takeaways

Key takeaways

- Custom local rules are very much possible!
- Interchangeability of rules
- Considerations for future success





09 Q&A

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