CORE: Authoring & Running Your Own Rules

Health Inspired, Quality Driven.

Roman Radelicki, Head Data Technology, June 2024
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- The author(s) have no real or apparent conflicts of interest to report.
Speaker

Roman Radelicki
Head Data Technology
SGS

- Member of the CDISC CORE community group
- Consultancy regarding CDISC CORE
- CDISC authorized instructor
SGS’s CDISC CORE experts

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

Talk to us!
clinicalresearch@sgs.com

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
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

Output report

CDISC Datasets Metadata

Community Governance

End User

Community

Rule Editor

SGS
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:
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 sdtnig -v 3-4 -d c:\core_data\data\`
Creating custom CORE rules

Rules Engine commands:

- `-dxp`: 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
Creating custom CORE rules

End User

Local Rule Editor

CDISC Datasets
Metadata

Other datasets

Output report

Local Rules

CORE

OPEN RULES ENGINE

Community Governance

Community

Rule Editor

Local Rule Editor

SGS
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
Creating custom CORE rules

Diagram:
- End User
- Local Rule Editor
- Local Rules
- CDISC Datasets
- Metadata
- Other datasets
- Output report
- CORE engine
- Community Governance
- Community
- Rule Editor
- CORE LIBRARY
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)
Case #1

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

Core:
  Id: ROMAN-0001
  Status: Draft
  Version: '1'
  Description: Verify that --ORRES or --STRESC or --STRESN is not empty when --NRIND is completed
  Executability: Fully Executable
  Outcome:
    Message: --ORRES or --STRESC or --STRESN should be completed when --NRIND is completed
  Rule Type: Record Data
  Scope:
  Classes:
    Include:
      - FINDINGS
  Domains:
    Include:
      - ALL
  Sensitivity: Record
Case #1

- Export the rule in YAML format

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

Core:
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  Status: Draft
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Rule Type: Record Data

Scope:
  Classes:
    Include:
      - FINDINGS
  Domains:
    Include:
      - ALL

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

<table>
<thead>
<tr>
<th>Conformance Details</th>
<th>Dataset Details</th>
<th>Issue Summary</th>
<th>Issue Details</th>
<th>Rules Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORE-ID</td>
<td>Version</td>
<td>CDISC RuleID</td>
<td>Message</td>
<td></td>
</tr>
<tr>
<td>ROMAN-0001</td>
<td>1</td>
<td>CG0176</td>
<td>--ORRES or --STRESC or --STRESN should be completed when --NRIND is completed</td>
<td></td>
</tr>
<tr>
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<td></td>
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**Status:** SUCCESS

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<th>Issues</th>
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<td>VSORRES or VSSTRESC or VSSTRESN should be completed when VSNRIND is completed</td>
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<table>
<thead>
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<th>Conformance Details</th>
<th>Dataset Details</th>
<th>Issue Summary</th>
<th>Issue Details</th>
<th>Rules Report</th>
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</thead>
<tbody>
<tr>
<td>CORE-ID</td>
<td>Message</td>
<td>Dataset</td>
<td>USUBJID</td>
<td>Record</td>
</tr>
<tr>
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<td>VSORRES or VSSTRESC or VSSTRESN should be completed when VSNRIND is completed</td>
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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
## Case #2

<table>
<thead>
<tr>
<th>CORE-ID</th>
<th>Message</th>
<th>Dataset</th>
<th>USUBJID</th>
<th>Record</th>
<th>Variable(s)</th>
<th>Value(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROMAN-0002</td>
<td>AGE greater than 40 and SEX is equal to &quot;M&quot; or AGE greater than 41 and SEX is equal to &quot;F&quot;.</td>
<td>DM</td>
<td>SGS-DRG-001-01-S001</td>
<td>1</td>
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<td>42.0, F</td>
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<td>DM</td>
<td>SGS-DRG-001-01-S014</td>
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<tr>
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<td>DM</td>
<td>SGS-DRG-001-01-S024</td>
<td>9</td>
<td>AGE, SEX</td>
<td>48.0, M</td>
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<tr>
<td>ROMAN-0002</td>
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<td>DM</td>
<td>SGS-DRG-001-01-S033</td>
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<td>45.0, F</td>
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<td>DM</td>
<td>SGS-DRG-001-01-S034</td>
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<td>55.0, F</td>
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<td>DM</td>
<td>SGS-DRG-001-01-S039</td>
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<td>SGS-DRG-001-01-S047</td>
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<td>SGS-DRG-001-01-S048</td>
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<td>SGS-DRG-001-01-S049</td>
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<tr>
<td>ROMAN-0002</td>
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<td>SGS-DRG-001-01-S052</td>
<td>23</td>
<td>AGE, SEX</td>
<td>51.0, M</td>
</tr>
</tbody>
</table>
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
Case #3

- non-CDISC clinical data such as external vendor data

<table>
<thead>
<tr>
<th>CORE-ID</th>
<th>Version</th>
<th>CDISC RuleID</th>
<th>Message</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROMAN-0003</td>
<td>1</td>
<td>CG0176</td>
<td>No result unit completed</td>
<td>SUCCESS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CORE-ID</th>
<th>Message</th>
<th>Dataset</th>
<th>USUBJID</th>
<th>Record</th>
<th>Sequence</th>
<th>Variable(s)</th>
<th>Value(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROMAN-0003</td>
<td>No result unit completed</td>
<td>LABO</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>Screenid, Units, testname, value</td>
<td>SGS-DRG-001-01-S003, PROTEIN, 8.0</td>
</tr>
<tr>
<td>ROMAN-0003</td>
<td>No result unit completed</td>
<td>LABO</td>
<td>1</td>
<td>9</td>
<td>9</td>
<td>Screenid, Units, testname, value</td>
<td>SGS-DRG-001-01-S009, MAGNESIUM, 2.1</td>
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</table>
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

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Roman Radelicki
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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]
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...
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.
08 Key takeaways
Key takeaways

- Custom local rules are very much possible!
- Interchangeability of rules
- Considerations for future success
09 Q&A
Contact us

SGS Health Science
Europe +32 15 27 32 45
Americas + 1 877 677 2667

clinicalresearch@sgs.com
www.sgs.com/healthscience