

When you need
to be sure



Health & Nutrition, Health Science

SI03: Our Road to Adopting CORE: an Implementation Journey in SDTM Dataset Validation

Health Inspired, Quality Driven

Speaker

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Marisa Wyckmans started her career in clinical data management 18 years ago and has held various positions within the Data Management team at SGS Health Science. In her current role as Data Management Systems and Process Manager, she is DM expert and point of contact concerning DM systems and processes used within SGS. She is also CDISC Open Rules volunteer since September 2021.





Disclaimer and disclosures

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Agenda

- 01 CDISC Open Rules Concept
- 02 Implementation Journey
- 03 Glimpse to the Future
- 04 Conclusion



01 CDISC Open Rules Concept



CDISC Open Rules Concept, Goals and Objectives



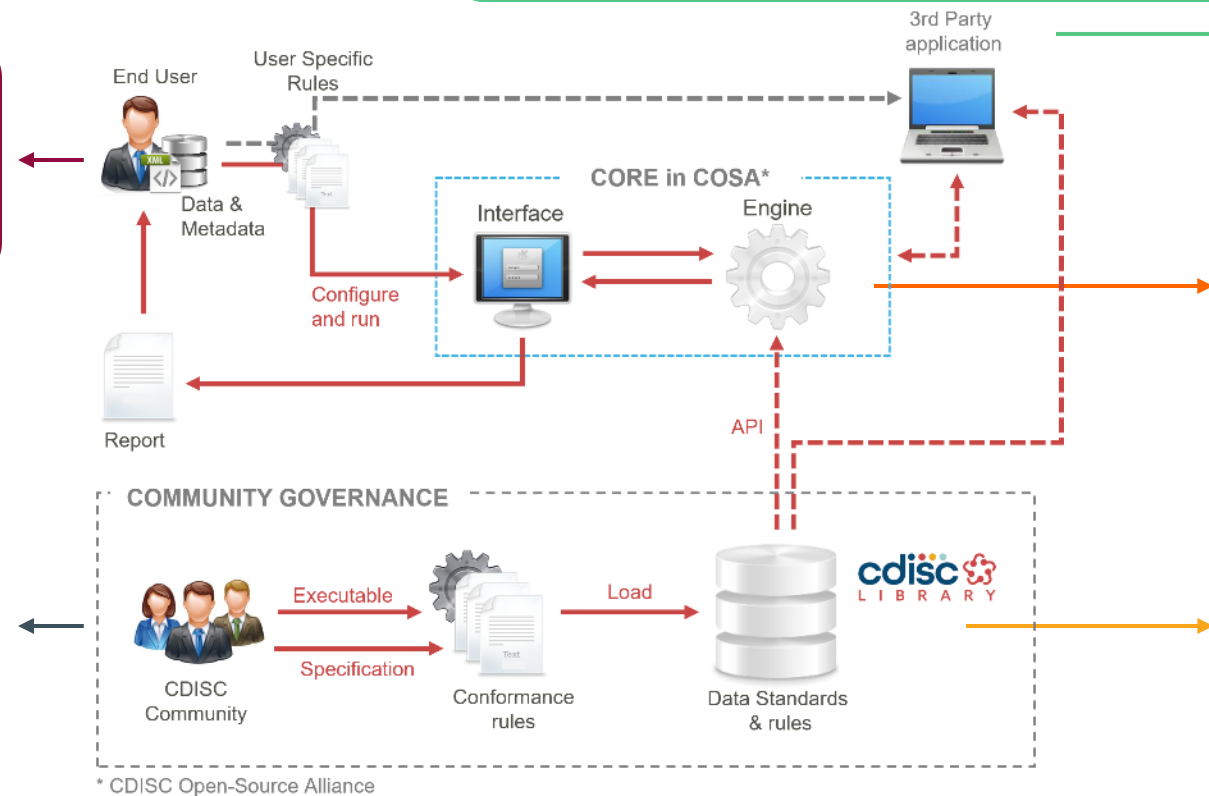
Development of validation applications by third party vendors

Review of validation output including company defined custom rules

Rules Engine retrieves conformance rules and validates data

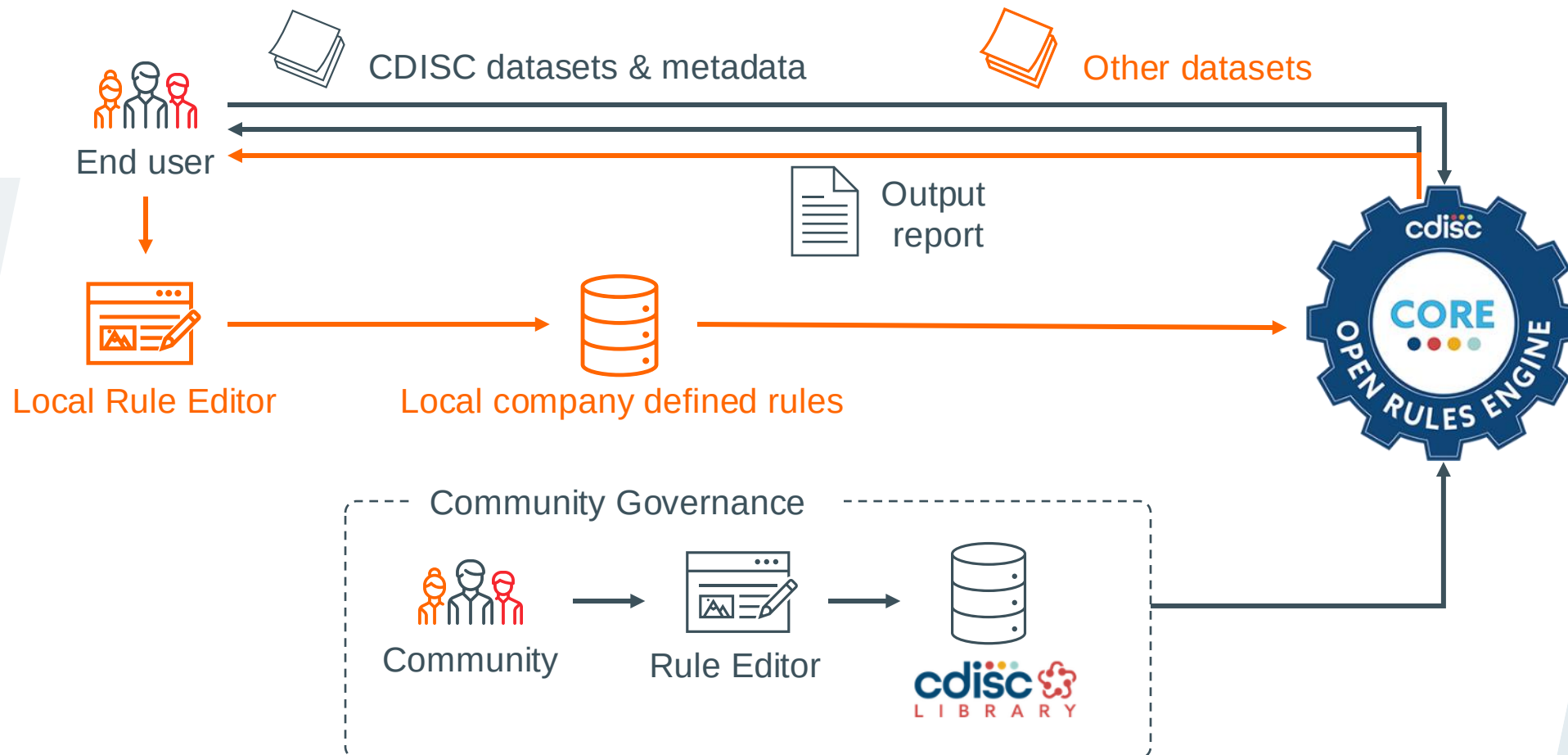
Define and create machine executable conformance rules in Rule Editor

Published conformance rules stored in CDISC library



The Power of CDISC Open Rules: Impact & Added Value

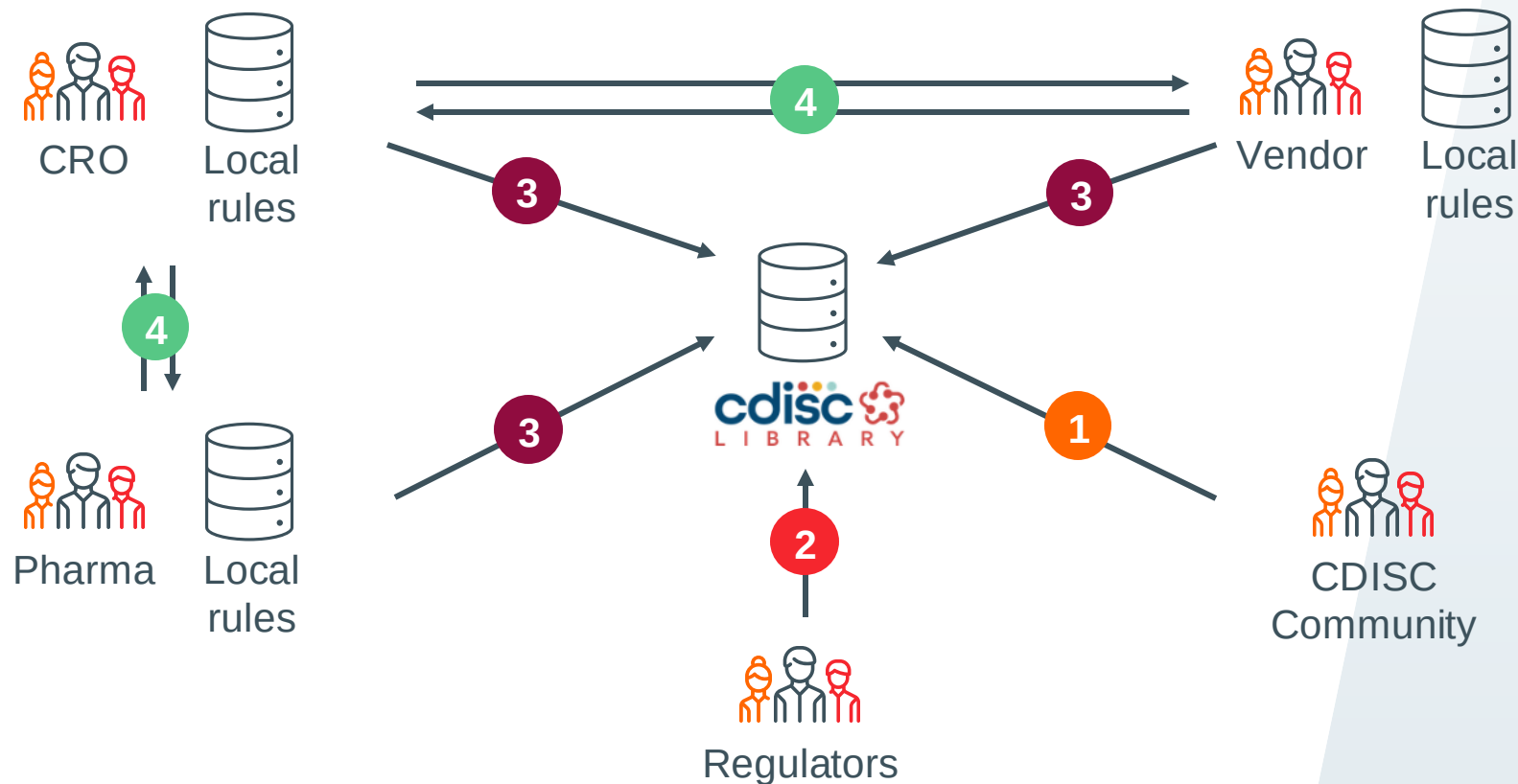
Integration of company defined rules



The Power of CDISC Open Rules: Impact & Added Value

Exchange of company defined rules

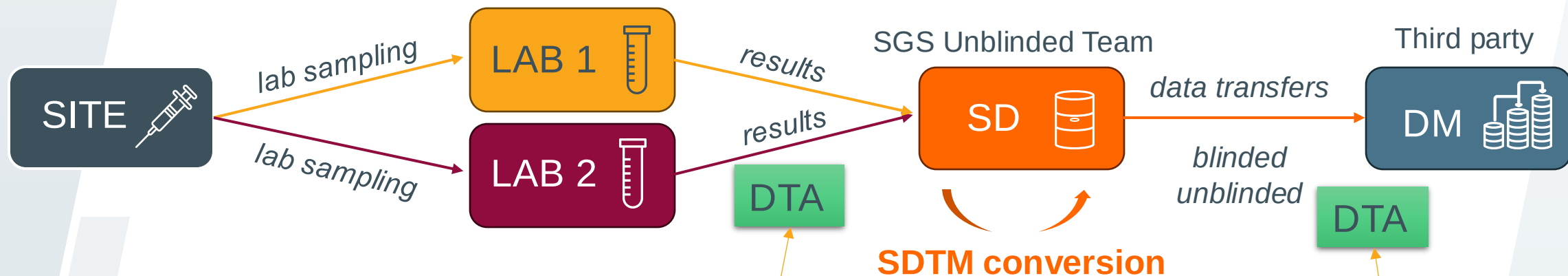
- 1 CDISC Rule Governance
- 2 Collaboration Regulators
- 3 Contribution to CDISC rules
- 4 Exchange of company defined rules



02 Implementation Journey



Unblinding Data Flow



Validation Incoming Data

- Structure = DTA
- Content = DTA
- Stable for conversion

Validation Outgoing Data

- Structure = DTA
- Content = DTA
- SDTM Conformance
- Regulatory Compliance

Lab samples

- PK samples (blood, stool, urine)
- Blood samples for biomarker analysis or immunogenicity
- ...

Data files in different structures and formats

- csv
- sas7bdat
- ...

SDTM datasets

- PC and PP SDTM dataset
- LB and IS SDTM dataset
- ...

A New Data Validation Tool

C
U
R
R
E
N
T

Complex rule
output = a list
of data = labor
intensive

Rule creation
requires
programming
knowledge and
a lot of
documentation

New SDTM or
regulatory
conformance
rules need to
be added
manually = no
automatization

Rules combine
different
aspects to be
validated =
challenging

Outgoing
SDTM
converted
datasets
validated via
tool, incoming
transfer
validated
manually

N
E
W

Rules that
generate
simple output
Conformance =
no output = no
work

Easy creation
of rules, low
code, efficient
workflow

Automatic
upload of new
SDTM or
regulatory
conformance
rules

Split up rules in
validation
purpose = clear
categories

Option to
validate
incoming
vendor file and
outgoing SDTM
converted
dataset

Is CDISC Open Rules our Superhero?



```
Check:
all:
  - name: --ELTM
    operator: exists
  - name: --TPTREF
    operator: not_exists
Core:
  Id: CORE-000167
  Status: Published
  Version: '1'
Description: Raise an error when --ELTM is present but --TPTREF is not present in dataset.
Executability: Fully Executable
Outcome:
  Message: --TPTREF must be present when --ELTM is present in a dataset
Output Variables:
  - --ELTM
  - --TPTREF
```

Non-conformant → output
Conformant → no output

Is CDISC Open Rules our Superhero?



1 – Write Rule



2 – Create Test Data



3 – QC Rule Description



4 – Validate Rule Output



5 – Publish Rule

Is CDISC Open Rules our Superhero?



■ CDISC Open Rules Project Objectives on CORE | CDISC

The CORE Project objectives are to:

- Ensure each standard has a set of unambiguous, executable Conformance Rules
- Ensure consistency across Conformance Rule implementations
- Expedite the availability of executable Conformance Rules for new Foundational Standards
- Create executable Conformance Rules vetted by the CDISC standards development teams
- Create a Reference Implementation of an open-source engine that executes the Rules
- Release the open-source engine under the **CDISC Open-Source Alliance (COSA)**

■ FDA collaboration

CDISC is Proud to Announce a Research Collaboration to Incorporate FDA Business Rules into CDISC's Open Rules Engine (CORE)

Austin, TX – January 16, 2024 – CDISC is proud to announce a research collaboration with the U.S. Food and Drug Administration's Office of Translational Sciences in the Center for Drug Evaluation and Research and Office of Regulatory Operations in the Center for Biologics Evaluation and Research to incorporate FDA Business Rules into CDISC's Open Rules Engine (CORE).

Is CDISC Open Rules our Superhero?



1. SDTM Conformance ✓

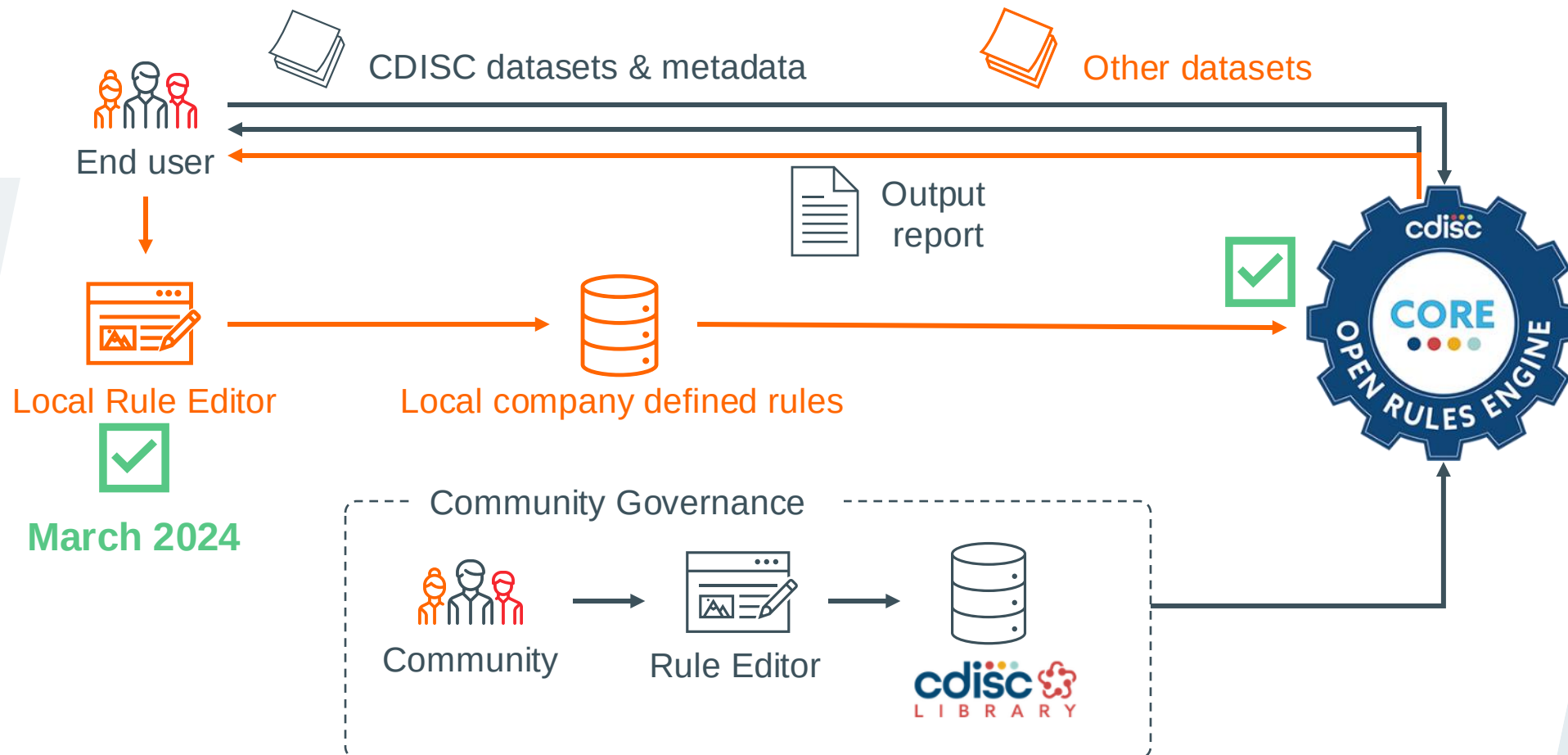
2. Regulatory Compliance ✓

3. Data Content ?

4. DTA Compliance ?

The SD Rule Package

CDISC governed rules meet SGS defined rules

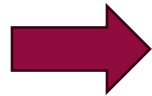


The SD Rule Package

CDISC governed rules meet SGS defined rules

- Define rules for SD team based on checks in old tool
 - Analyze rule purpose
 - Crosscheck with CDISC Conformance & FDA Business Rules
 - Fill gaps with SGS Custom Rules

TOOL.4.43 The tool should create an overview where the STRESC, STRESN and ORRES contents are not the same. If no differences → 'no issues'



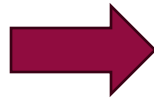
Rule Category	Organisation	Rule Type	Domain	Full description
SDTM Conformance	CDISC	CG0397	Findings	Check that --STRESC is completed when either --ORRES is provided or --DRVFL = 'Y'
SDTM Conformance	FDA	FDAB031 (CORE rule pending)	Findings	Standardized Result in Numeric Format should be populated whenever it is applicable.
SDTM Conformance	SGS	Custom CORE	Findings	Check when --ORRESU and --STRESU are not completed and --ORRES and --STRESC are not equal that this is expected.
SDTM Conformance	SGS	Custom CORE	Findings	Check if --ORRESU and --STRESU are equal that --ORRES and --STRESC are equal.
SDTM Conformance	SGS	Custom CORE	Findings	Check that --STRESN is not populated when --STRESC is not numeric.

The SD Rule Package

CDISC governed rules meet SGS defined rules

- Define rules for SD team based on checks in old tool

TOOL.4.14 The tool should create an overview of all test codes where ORRES (<,>) is BLQ/ALQ; ORRES, STRESN, LLOQ and count is also shown. If ORRES is empty, no output needed.



Rule Category	Organisation	Rule Type	Domain	Full description
Data Review	SGS	Custom CORE	Findings	Check that value in --STRESN is equal to or above --LLOQ.
Data Review	SGS	Custom CORE	Findings	Check that value in --STRESN is equal to or below --ULOQ.
Data Review	SGS	Custom CORE	Findings	Check if --STRESC contains '<' that result is in alignment with --LLOQ.
Data Review	SGS	Custom CORE	Findings	Check if --STRESC contains '>' that result is in alignment with --ULOQ.
Data Review	SGS	Custom CORE	Findings	Check that --LLOQ and --ULOQ are completed in the same unit as the --STRESC and that the dilution factor (if applicable) is taken into account.

The SD Rule Package

CDISC governed rules meet SGS defined rules

- Define rules for SD team based on checks in old tool

TOOL.5.1 The tool should create an overview of the different TESTCD, TEST, SPCCND, SPEC, CAT, SCAT, NAM, STRESU, ORRESU, STAT, METHOD values used in the dataset.



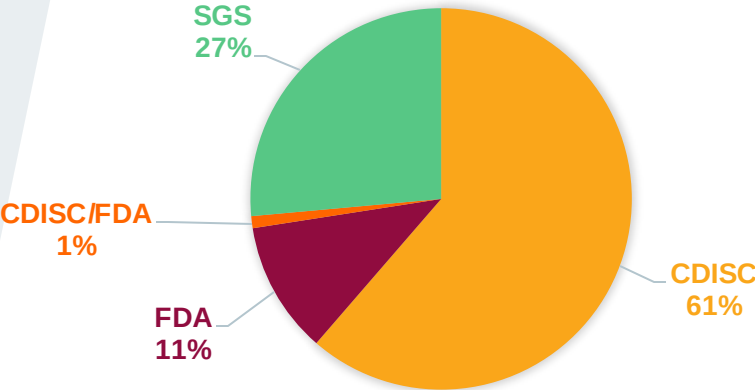
Rule Category	Organisation	Rule Type	Domain	Full description
DTA Compliance	SGS	Custom CORE	Findings	Check that the combination --TEST, --TESTCD, --CAT, --SCAT, --ORRESU, --STRESU, --SPEC, --METHOD in the outgoing SDTM dataset is correct and as expected per DTA combination
DTA Compliance	SGS	Custom CORE	Findings	Check that --NAM in the outgoing SDTM dataset is correctly completed as specified in the DTA

The SD Rule Package

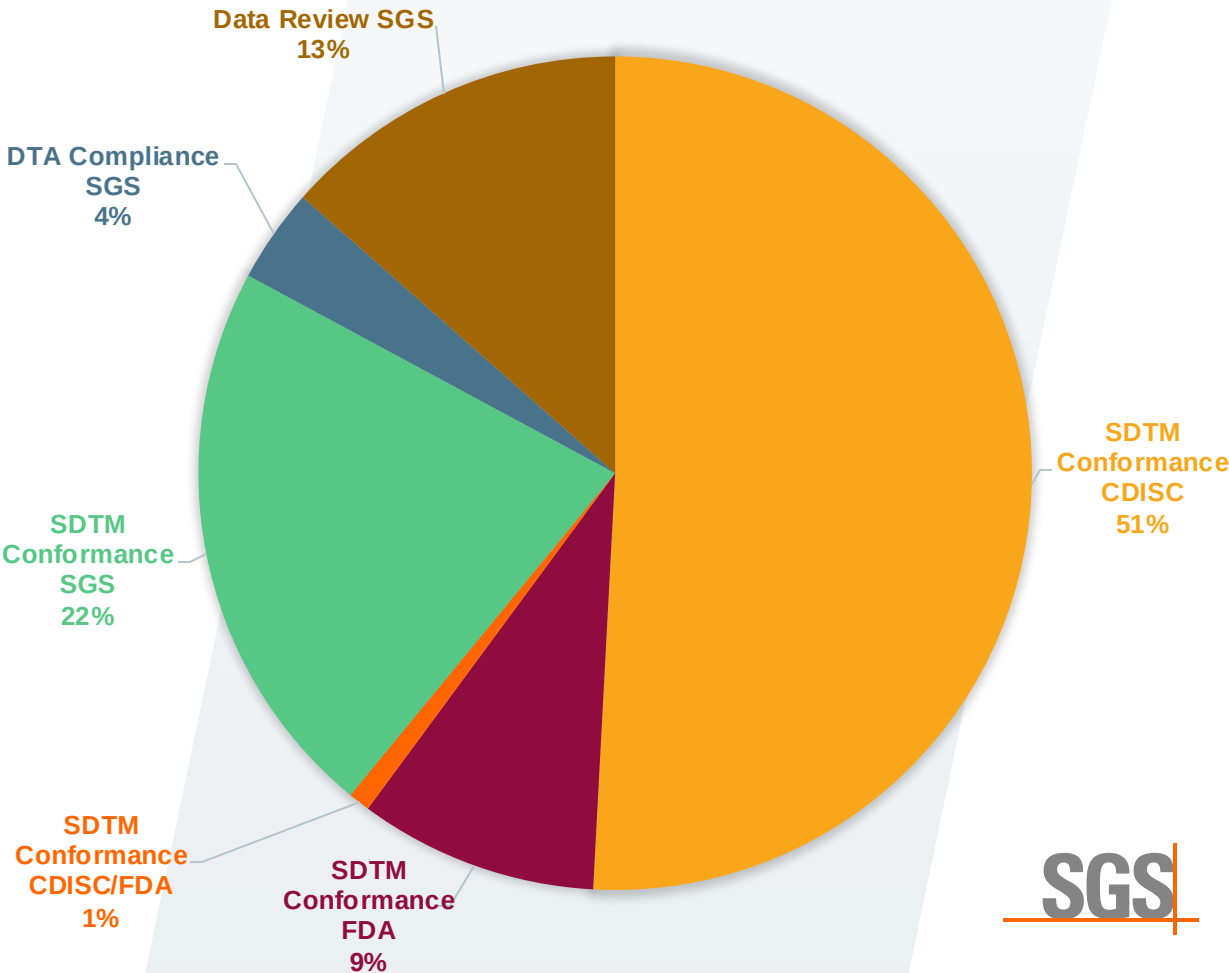
CDISC governed rules meet SGS defined rules

Category	Authority	# Rules
SDTM Conformance	CDISC	181
	FDA	33
	CDISC/FDA	3
	SGS	78
DTA Compliance	SGS	13
Data Review	SGS	48
Total		356

SDTM CONFORMANCE

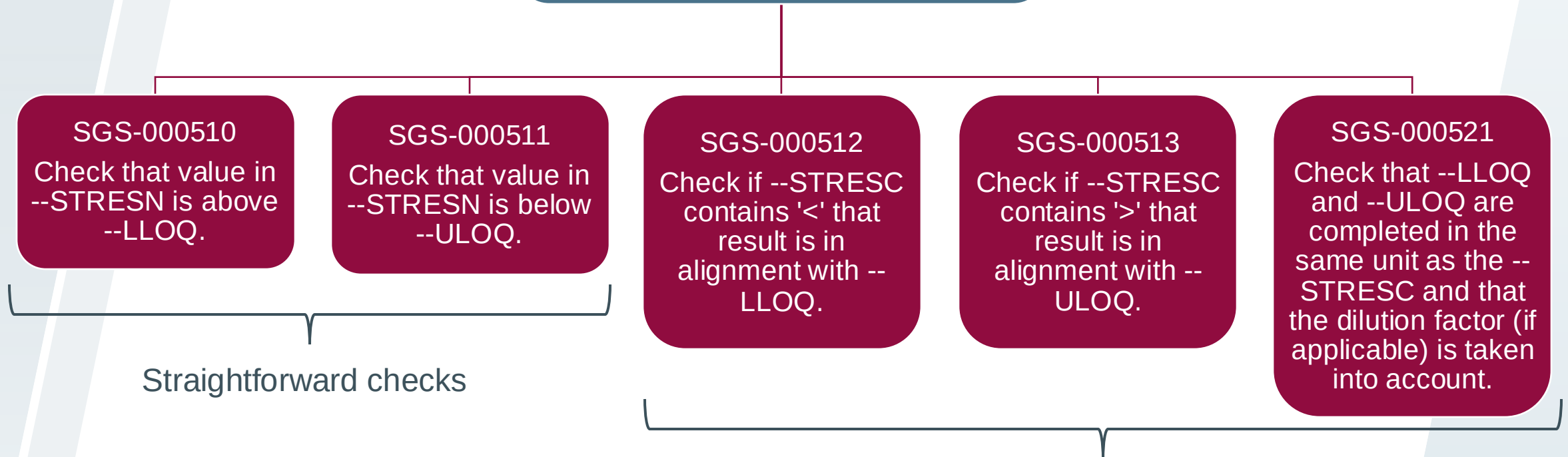


STATISTICS



Rule writing – example: SGS Data Content Rules

The tool should create an overview of all test codes where ORRES (<,>) is BLQ/ALQ; ORRES, STRESN, LLOQ and count is also shown (only for the SGS implementation guide). If ORRES is empty, no output needed.



Rule writing – example 1: SGS Data Content Rules

- SGS-000512: Check if --STRESC contains '<' that result is in alignment with --LLOQ.

1. Write

2. Test data

Unique Subject Identifier	Pharmacokinetic Test Short	Result or Finding in Original	Original Units	Character Result/Finding in Std	Numeric Result/Finding in	Standard Units	Specimen Material Type	Lower Limit of Quantitation	Visit Name	Planned Time Point Name
Char	Char	Char	Char	Char	Num	Char	Char	Num	Char	Char
50	50	50	50	50	8	50	50	8	50	50
TEST-001	ANALYTE	<10.0	ng/mL	<10.0		ng/mL	PLASMA	10	DAY1	PRE-DOSE
TEST-001	ANALYTE	<10.0	ng/mL	<10.0		ng/mL	URINE	10	DAY1	0.5H
TEST-001	ANALYTE	<10.0	ng/mL	<10.0		ng/mL	URINE	10	DAY1	1H
TEST-001	ANALYTE	<10.0	ng/mL	<10.0		ng/mL	URINE	10	DAY1	2H
TEST-001	ANALYTE	<10.0	ng/mL	<10.0		ng/mL	URINE	10	DAY1	3H
TEST-001	ANALYTE	12.1	ng/mL	12.1	12.1	ng/mL	URINE	10	DAY1	4H
TEST-001	ANALYTE	11.8	ng/mL	11.8	11.8	ng/mL	URINE	10	DAY1	6H

3. Check results

Success!

```
+ [Icons] Search YAML...

Rule Ids      Creator      Standards      Orgs
Search...    Search...      Search...      Search...

SGS-000512    Wyckmans, Marisa (Mechelen)    SDTMIG    SGS

1 Authorities:
2 > - Organization: 'SGS' ...
25 Check:
26 all:
27   - name: --STRESC
28     operator: contains
29     value: '<'
30 Core:
31   Status: Draft
32   Version: '1'
33 Description: Check if --STRESC contains '<' that result is in alignment
34 with --LLOQ
35 Executability: Partially Executable - Possible Overreporting
36 Outcome:
37   Message: --STRESC contains '<'. Check output to assess whether this is
38   in
39   alignment with --LLOQ.
40   Output Variables:
41     - --STRESC
42     - --LLOQ
43     - VISIT
44     - --TPT
45 Rule Type: Record Data
46 Scope:
47   Classes:
48     Include:
49       - FINDINGS
50   Domains:
51     Include:
52       - ALL
```

```
"PC" : [ 1 item
  0 : { 5 items
    "executionStatus" : "success"
    "domain" : "PC"
    "variables" : [ 4 items
      0 : "PCLLOQ"
      1 : "PCSTRESC"
      2 : "PCTPT"
      3 : "VISIT"
    ]
    "message" :
      "PCSTRESC contains '<'. Check output to assess whether this is in alignment
      with PCLLOQ."
    "errors" : [ 30 items
      0 : { 3 items
        "value" : { 4 items
          "PCSTRESC" : "<10.0"
          "PCLLOQ" : 10
          "VISIT" : "DAY1"
          "PCTPT" : "PRE-DOSE"
        }
        "row" : 1
        "USUBJID" : "TEST-001"
      }
    ]
  }
]
```

Rule writing – example: SGS DTA Compliance Rules

The tool should create an overview of the different TESTCD, TEST, SPCCND, SPEC, CAT, SCAT, NAM, STRESU, ORRESU, STAT, METHOD values used in the dataset.

SGS-DTA001

Check that the combination --TEST, --TESTCD, --CAT, --SCAT, --ORRESU, --STRESU, --SPEC, --METHOD in the outgoing SDTM dataset is correct and as expected per DTA combination

SGS-DTA002

Check that --NAM in the outgoing SDTM dataset is correctly completed as specified in the DTA

Rule writing – example 2: DTA Compliance Rules

- SGS-DTA001: Check that the combination --TEST, --TESTCD, --CAT, --SCAT, --ORRESU, --STRESU, --SPEC, --METHOD in the outgoing SDTM dataset is correct and as expected per DTA combination

1. Data

Filename	Dataset Name	Label
dtaspec.xpt	DTASPEC	Data Transfer Agreement Specs
dtatest.xpt	DTATEST	DTA Test Specifications
pc.xpt	PC	Pharmacokinetics Concentrations

PCTESTCD	PCTEST	PCCAT	PCSCAT	PCSPEC	PCMETHOD	PCORRESU	PCSTRESU
Test Short Name	Test Name	Test Category	Test Subcategory	Specimen Material Type	Method of Test or Examination	Original Units	Standard Units
Char	Char	Char	Char	Char	Char	Char	Char
50	50	50	50	50	50	50	50
ANALYTE	Analyte	PK SAMPLING	SAMPLE1	PLASMA		ng/mL	ng/mL
ANALYTE	Analyte			URINE		ng/mL	ng/mL

STUDYID	DOMA	USUBJID	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTRES	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCLLOQ	VISIT	PCTPT
Study Identifier	Domain Abbreviation	Unique Subject Identifier	Pharmacokinetic Test Short	Pharmacokinetic Test Name	Test Category	Test Subcategory	Result or Finding in Original	Original Units	Character Result/Finding in Std	Numeric Result/Finding in	Standard Units	Vendor Name	Specimen Material Type	Method of Test or Examination	Lower Limit of Quantitation	Visit Name	Planned Time Point Name
Char	Char	Char	Char	Char	Char	Char	Char	Char	Char	Num	Char	Char	Char	Char	Num	Char	Char
50	50	50	50	50	50	50	50	50	50	8	50	50	50	50	8	50	50
TEST STUDY	PC	TEST-001	ANALYTE	Analyte	PK	SAMPLE1	<10.0	ng/mL	<10.0		ng/mL	SGS LAB	PLASMA		10	DAY1	PRE-DOSE
TEST STUDY	PC	TEST-001	ANALYTES	Analytes			<10.0	ng/mL	<10.0		ng/mL	SGS LAB	URINE		10	DAY1	6H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL	SGS LAB	SERUM		10	DAY1	8H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte	PK		<10.0	ng/mL	<10.0		ng/mL	SGS LAB	URINE		10	DAY1	8H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte		2	<10.0	ng/mL	<10.0		ng/mL	SGS LAB	URINE		10	DAY1	8H
TEST STUDY	PC	TEST-001	ANALYTES	Analytes			12.1	ng/mL	12.1	12.1	ng/mL	SGS LAB	URINE		10	DAY1	6H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			11.8	ng/L	11.8	11.8	ng/mL	SGS LAB	URINE		10	DAY1	8H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		g/mL	SGS LAB	URINE		10	DAY1	8H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL	SGS LAB	PLASMA	TEST METHOD	10	DAY8	

8 records don't match DTA test specifications

Rule writing – example 2: DTA Compliance Rules

- SGS-DTA001: Check that the combination --TEST, --TESTCD, --CAT, --SCAT, --ORRESU, --STRESU, --SPEC, --METHOD in the outgoing SDTM dataset is correct and as expected per DTA combination

2. Write

Rule Ids	Creator	Standards	Orgs
Search...	Wyckmans, M X	Search...	Search...
SGS-DTA001	Wyckmans, Marisa (Mechelen)		SGS

```
1 Authorities:
2   - Organization: 'SGS'
3 > Standards: ...
25 Check:
26   any:
27     - name: --TESTCD
28       operator: is_not_contained_by
29       value: $dta_testcd
30     - name: --TEST
31       operator: is_not_contained_by
32       value: $dta_test
33     - name: --CAT
34       operator: is_not_contained_by
35       value: $dta_cat
36     - name: --SCAT
37       operator: is_not_contained_by
38       value: $dta_subcat
39     - name: --SPEC
40       operator: is_not_contained_by
41       value: $dta_spectype
42     - name: --METHOD
43       operator: is_not_contained_by
44       value: $dta_method
45     - name: --ORRESU
46       operator: is_not_contained_by
47       value: $dta_origu
48     - name: --STRESU
49       operator: is_not_contained_by
50       value: $dta_standu
51 Core:
```

```
Version: 1
54 Description: Check that --TESTCD, --TEST, --CAT, --SCAT, --SPEC,
--ORRESU,
55 --STRESU are according to the DTA.
56 Executability: Fully Executable
57 Operations:
58   - domain: DTATEST
59     id: $dta_testcd
60     name: PCTESTCD
61     operator: distinct
62   - domain: DTATEST
63     id: $dta_test
64     name: PCTEST
65     operator: distinct
66   - domain: DTATEST
67     id: $dta_cat
68     name: PCCAT
69     operator: distinct
70   - domain: DTATEST
71     id: $dta_subcat
72     name: PCSCAT
73     operator: distinct
74   - domain: DTATEST
75     id: $dta_spectype
76     name: PCSPEC
77     operator: distinct
78   - domain: DTATEST
79     id: $dta_method
80     name: PCMETHOD
81     operator: distinct
82   - domain: DTATEST
83     id: $dta_origu
84     name: PCORRESU
85     operator: distinct
86   - domain: DTATEST
87     id: $dta_standu
88     name: PCSTRESU
89     operator: distinct
90 Outcome:
91   Message: Value of --TESTCD, --TEST, --CAT, --SCAT, --SPEC,
--ORRESU and/or
92   --STRESU does not match the value expected per DTA.
93 Rule Type: Record Data
94 Scope:
```

Rule writing – example 2: DTA Compliance Rules

- SGS-DTA001: Check that the combination --TEST, --TESTCD, --CAT, --SCAT, --ORRESU, --STRESU, --SPEC, --METHOD in the outgoing SDTM dataset is correct and as expected per DTA combination

3. Check results

```
"PC" : [ 1 item
  0 : { 5 items
    "executionStatus" : "success"
    "domain" : "PC"
    "variables" : [ 8 items
      0 : "PCCAT"
      1 : "PCMETHOD"
      2 : "PCORRESU"
      3 : "PCSCAT"
      4 : "PCSPEC"
      5 : "PCSTRESU"
      6 : "PCTEST"
      7 : "PCTESTCD"
    ]
  }
]
"message" :
"Value of PCTESTCD, PCTEST, PCCAT, PCSCAT, PCSPEC, PCORRESU and/or PCSTRESU
does not match the value expected per DTA."
```

Success!

```
"errors" : [ 8 items
  0 : { 3 items
    "value" : { 8 items
      "PCSTRESU" : "ng/mL"
      "PCCAT" : ""
      "PCSPEC" : "URINE"
      "PCTEST" : "Analytes"
      "PCORRESU" : "ng/mL"
      "PCMETHOD" : ""
      "PCTESTCD" : "ANALYTES"
      "PCSCAT" : ""
    }
    "row" : 2
    "USUBJID" : "TEST-001"
  }
]
```

```
1 : { 3 items
  "value" : { 8 items
    "PCSTRESU" : "ng/mL"
    "PCCAT" : ""
    "PCSPEC" : "SERUM"
    "PCTEST" : "Analyte"
    "PCORRESU" : "ng/mL"
    "PCMETHOD" : ""
    "PCTESTCD" : "ANALYTE"
    "PCSCAT" : ""
  }
  "row" : 3
  "USUBJID" : "TEST-001"
}
```

Rule writing – example 3: SGS DTA Compliance Rules

- SGS-DTA002: Check that --NAM in the outgoing SDTM dataset is correctly completed as specified in the DTA

Rule Ids	Creator	Standards	Orgs
Search...	Wyckmans, M x	Search...	Search...
SGS-DTA002	Wyckmans, Marisa (Mechelen)		SGS

1. Write

```
1 Authorities:
2 > - Organization: 'SGS' ...
25 Check:
26   any:
27     - name: --NAM
28       operator: empty
29     - name: --NAM
30       operator: is_not_contained_by
31       value: $dta_labname
32 Core:
33   Status: Draft
34   Version: '1'
35 Description: Check that --NAM is correctly completed as specified in
the DTA
36 Executability: Fully Executable
37 Operations:
38   - domain: DTASPEC
39   filter:
40     Name: PCNAM
41     id: $dta_labname
42     name: Values
43     operator: distinct
44 Outcome:
45   Message: --NAM is not correctly completed as specified in the DTA
46   Output Variables:
47     - --NAM
48     - $dta_labname
Rule Type: Record Data
```

2. Test data

Filename	Dataset Name	Label
dtaspec.xpt	DTASPEC	Data Transfer Agreement Specs
dtatest.xpt	DTATEST	DTA Test Specifications
pc.xpt	PC	Pharmacokinetics Concentrations

Name	Label	Values
Transfer Variable Name	Transfer Variable Name	Allowed Values
Char	Char	Char
50	50	50
STUDYID	Study Identifier	TEST STUDY
DOMAIN	Domain Abbreviation	PC
USUBJID	Unique Subject Identifier	
PCSEQ	Sequence Number	
PCGRPID	Group ID	
PCREFID	Reference ID	
PCSPID	Sponsor-Defined Identifier	
PCTESTCD	Pharmacokinetic Test Short Name	See DTA Test Specifications
PCTEST	Pharmacokinetic Test Name	See DTA Test Specifications
PCCAT	Test Category	See DTA Test Specifications
PCSCAT	Test Subcategory	See DTA Test Specifications
PCORRES	Result or Finding in Original Units	
PCORRESU	Original Units	See DTA Test Specifications
PCSTRESC	Character Result/Finding in Std Format	
PCSTRESN	Numeric Result/Finding in Standard Units	
PCSTRESU	Standard Units	See DTA Test Specifications
PCSTAT	Completion Status	
PCREASND	Reason Test Not Done	
PCNAM	Vendor Name	SGS LAB

Rule writing – example 3: SGS DTA Compliance Rules

- SGS-DTA002: Check that --NAM in the outgoing SDTM dataset is correctly completed as specified in the DTA

2. Test data

Filename	Dataset Name	Label
dtaspec.xpt	DTASPEC	Data Transfer Agreement Specs
dtatest.xpt	DTATEST	DTA Test Specifications
pc.xpt	PC	Pharmacokinetics Concentrations

STUDYID	DOMA	USUBJID	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTRES	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCLOQ	VISIT	PCTPT
Study Identifier	Domain Abbreviation	Unique Subject Identifier	Pharmacokinetic Test Short	Pharmacokinetic Test Name	Test Category	Test Subcategory	Result or Finding in Original	Original Units	Character Result/Finding in Standard	Numeric Result/Finding in Standard	Standard Units	Vendor Name	Specimen Material Type	Method of Test or Examination	Lower Limit of Quantitation	Visit Name	Planned Time Point Name
Char	Char	Char	Char	Char	Char	Char	Char	Char	Char	Num	Char	Char	Char	Char	Num	Char	Char
50	50	50	50	50	50	50	50	50	50	8	50	50	50	50	8	50	50
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL		URINE		10	DAY1	12H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL	SGS LAB1	PLASMA		10	DAY2	24H
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL	SGS LAB	PLASMA		10	DAY15	
TEST STUDY	PC	TEST-001	ANALYTE	Analyte			<10.0	ng/mL	<10.0		ng/mL	SGS LAB	PLASMA		10	DAY1	PRE-DOSE

3. Check results

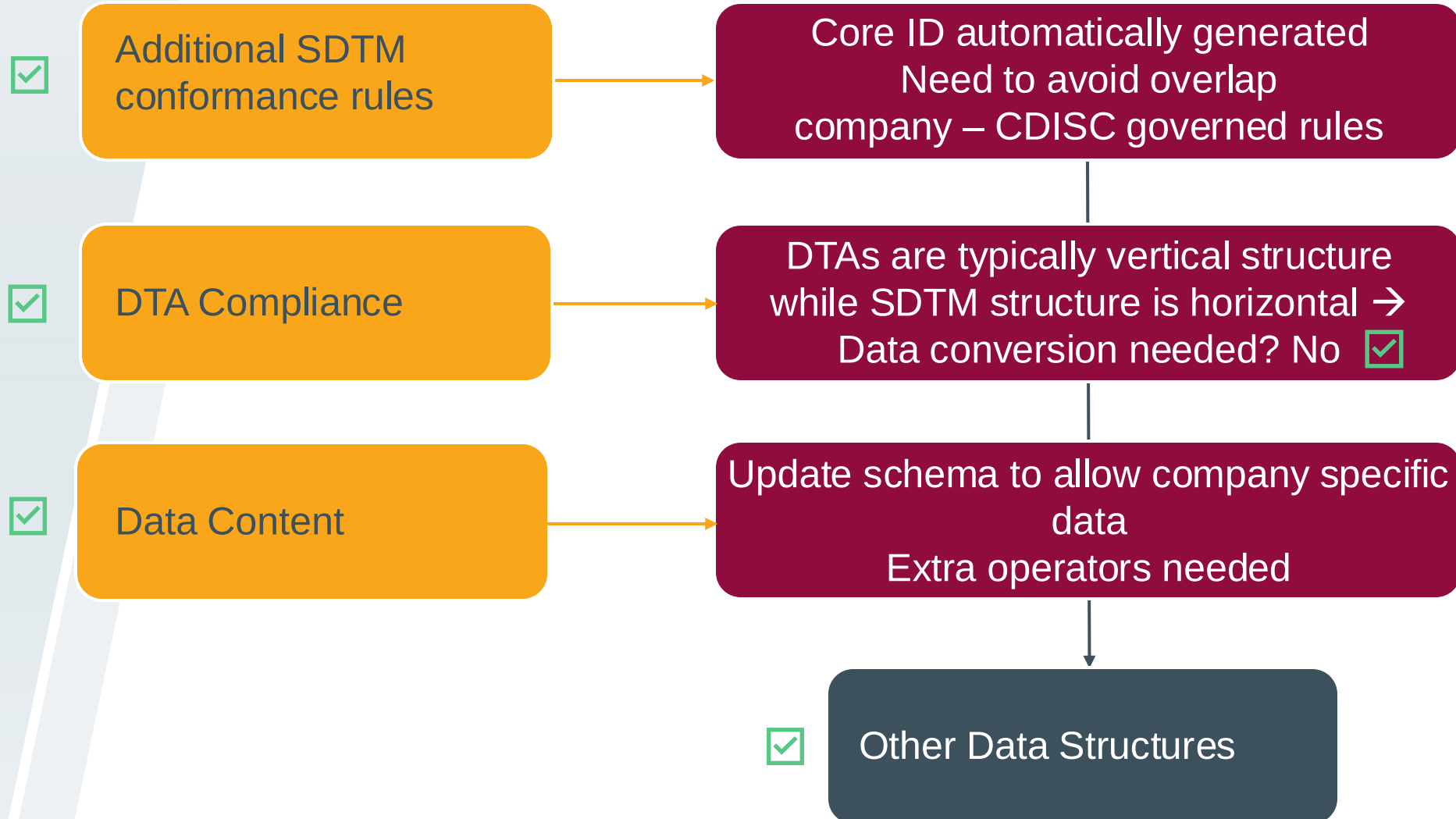
Success!

```
"PC" : [ 1 item
  0 : { 5 items
    "executionStatus" : "success"
    "domain" : "PC"
    "variables" : [ 1 item
      0 : "PCNAM"
    ]
    "message" : "PCNAM is not correctly completed as specified in the DTA"
  }
```

```
"errors" : [ 2 items
  0 : { 3 items
    "value" : { 1 item
      "PCNAM" : ""
    }
    "row" : 9
    "USUBJID" : "TEST-001"
  }
```

```
1 : { 3 items
  "value" : { 1 item
    "PCNAM" : "SGS LAB1"
  }
  "row" : 10
  "USUBJID" : "TEST-001"
}
```

Insights so far



Core ID	Status
Search...	Search...
CORE-000003	Published

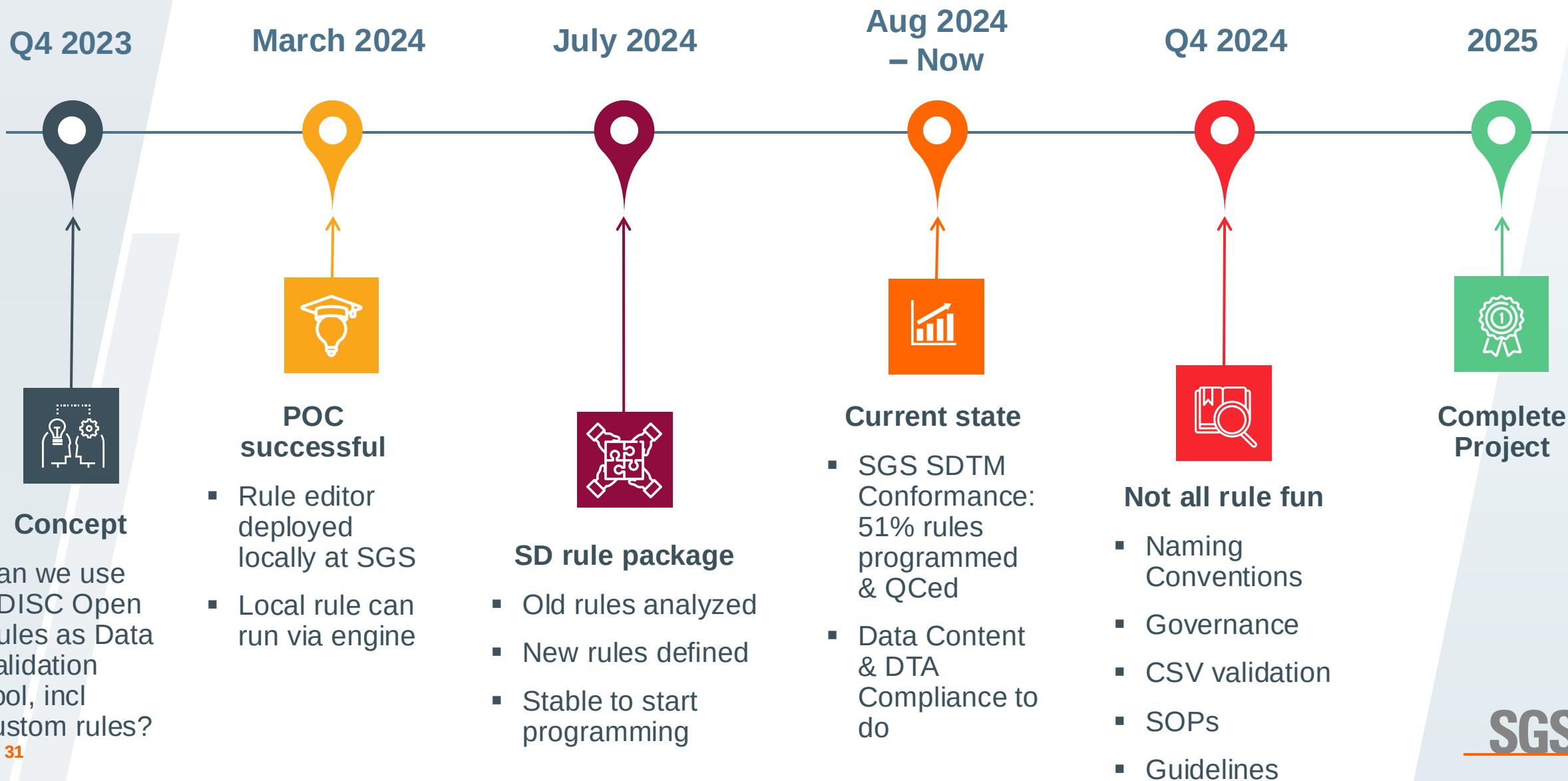
```
standards:  
- Name: 'SDTMIG'  
References:  
- Citations:  
  - Cited Guidance: ''...'  
Criteria:  
Origin: ''  
Release Notes: ''  
Rule Identifier:  
Id: 'SGS-000510'  
Version: '1'  
Validator Rule Message:  
Version: ''
```

Operator.md
Organization_CDISC.json
Organization_FDA.json
Organization_INTERNAL.json
Organization_PMDA.json
Rule_Type.json
Rule_Type.md

03 Glimpse to the Future



Timeline



The ideal validation platforms

- Rules Engine: configure parameters for validation via CLI
- Rule Engine generates output in Excel

Dataset	CORE-ID	Message	Issues
CM	CORE-000262	RFSTDTC in DM dataset is empty but CMSTRF is completed.	3
DM	CORE-000045	ARMNRS value is missing when ARMCD value is missing	95
DM	CORE-000046	ARMNRS is missing when ARM value is missing	95
DM	CORE-000223	ACTARMCD is empty, but ARMNRS is not completed.	95
DM	CORE-000224	ACTARM is empty, but ARMNRS is not completed.	95
EG	CORE-000249	Visit Day cannot be found in Trial Visit (TV) domain	117351
LB	CORE-000289	LBORRES is not a continuous measurement or Empty, when LBORNRI is not empty.	5
LB	CORE-000290	LBORRES is not a continuous measurement or Empty, when LBORNRO is not empty.	5
B	CORE-000298	LBORRES is not a numeric result/empty and LBSTNRLO is not empty.	5

- There is a need to
 - develop a more user friendly platform
 - To configure the validation
 - To review the output and track changes/add comments
 - include specific requirements



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...

04 Conclusion



Conclusion



- **Yes, we are on the right track!**
 - CDISC Open Rules does meet the requirements for our dataset validation
 - We believe this dream team has great potential
- **To be continued...**
 - Implementation project in progress
 - Perform gap analysis on current rule set and create new rules
 - Implement this not only for unblinding data but for all data
 - Further development of code (editor + engine) → discussions with CDISC needed based on our findings

SGS Teamwork

- SGS CORE Programming Team:
Hannes De Bondt, Chris Fransen, Jeroen Gielen, Roman Radelicki
- SGS CORE Rules Team:
Els Crijns, Els Janssens, Cemile Kocoglu, Niels Schrauwen, Hannelore Thimpont, Ovia Thirukkumaran

Teamwork makes
our dream work





Questions?

Visit us at booth 8

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