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Developing and Implementing CDISC CORE: a Data Managers Testimonial

Presented by Els Janssens, Executive Manager Secure Data Office
Data Management, SGS Health Science



Meet the Speaker

Els Janssens

Title: Executive Manager Secure Data Office

Organization: SGS Health Science

Els Janssens has more than 10 years of experience in the field of Clinical Data Management and CDISC SDTM standards (pharma and CRO). In her current role as Executive Manager Secure Data Office, she is responsible for the overall management of a dedicated unblinded team within SGS Data Management.

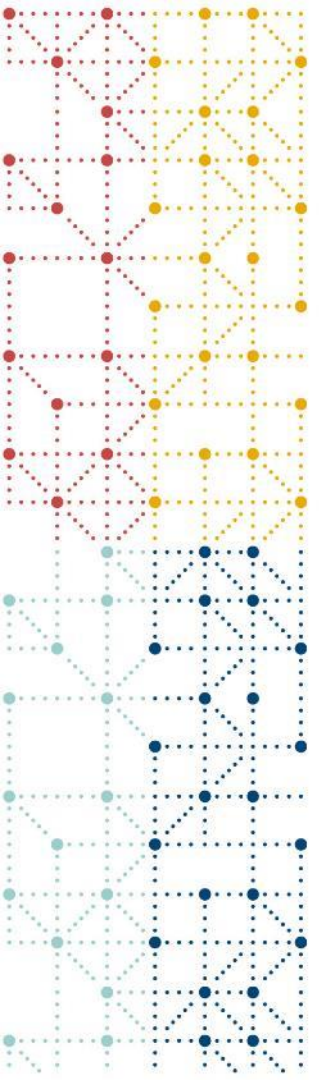
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC and SGS.*
- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. Introduction
2. To CORE or not to CORE?
3. Project Evolution
4. HardCORE Practice
5. Key Learnings
6. Future Development



1. Introduction

Introduction

Global Mission

- Data packages of high quality
- Clear & fast analysis and reporting
- Successful submission

Reality

- Increased trial complexity
- Several regulatory requirements
- Flexibility and adaptability needed
- Fast, faster, fastest



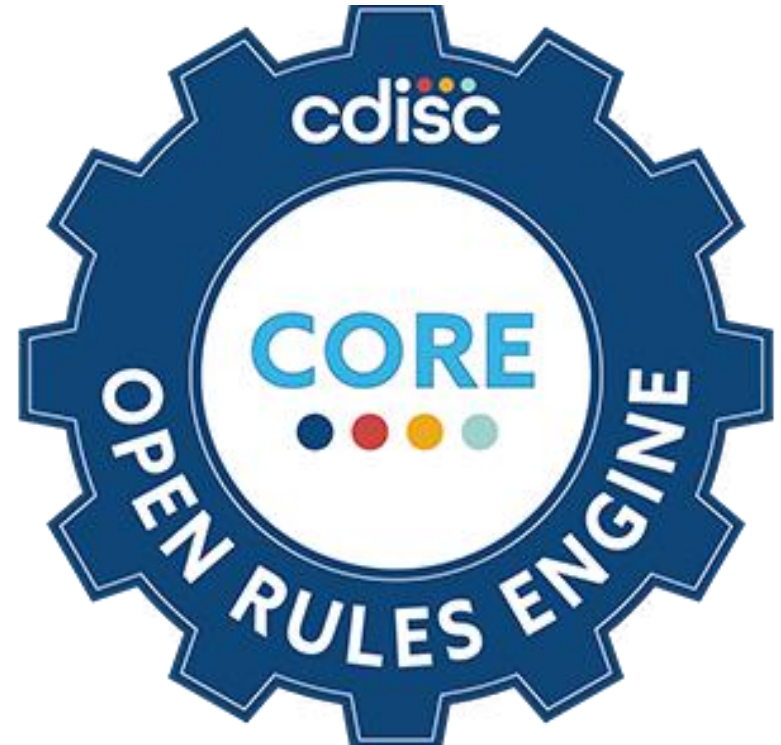
Introduction

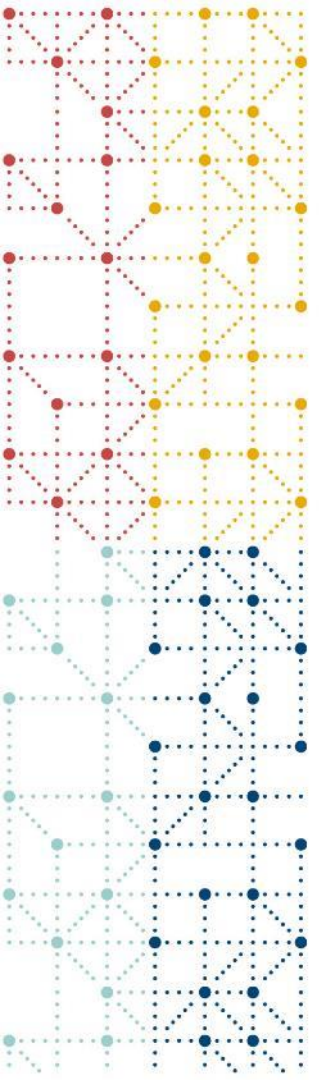
Global Mission

- Data packages of high quality
- Clear & fast analysis and reporting
- Successful submission

Reality

- Increased trial complexity
- Several regulatory requirements
- Flexibility and adaptability needed
- Fast, faster, fastest
- CDISC CORE





2. To CORE or not to CORE?

This should not be a question

To CORE or not to CORE?

Company



- Daily validation of data packages
- CDISC + regulatory + in-house developed rules
- Rules that are up to date with latest standards
- Rules that are unambiguous
- Validation of only parts of the data (e.g. blinded data)
- Achieve best quality in the most efficient way
- Open Source

To CORE or not to CORE?

Personal



- Expand knowledge of CDISC standards
- Understand how rules are defined and developed @CDISC
- Connect with people from the industry and exchange thoughts
- Contribute to the development of the industry

To CORE or not to CORE?

Professional experience as data manager



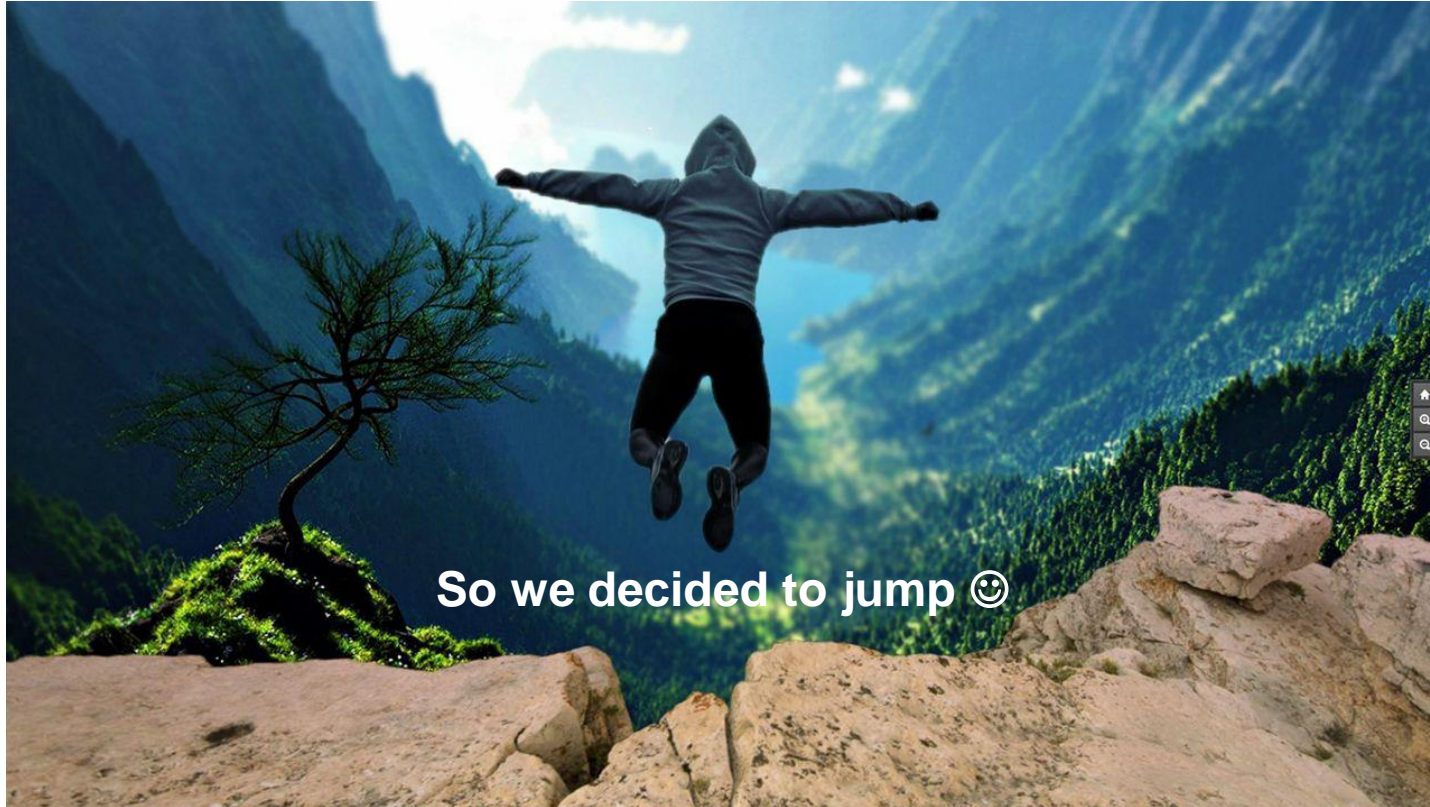
- eCRF review - data cleaning
- SDTM set-up and validation
- Development and validation of data cleaning rules (on SDTM)

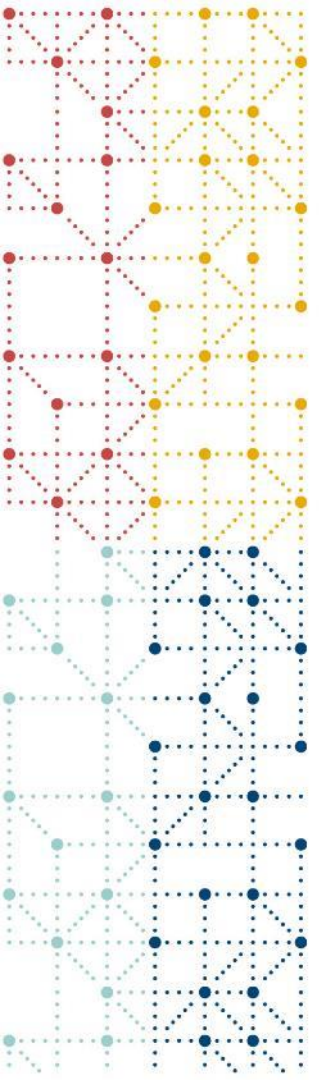
Cold Feet



- First time volunteering - What is expected from me?
- Am I smart enough? - Imposter syndrome
- What if they only need programmers? - I know some basic SQL but...

To CORE or not to CORE?



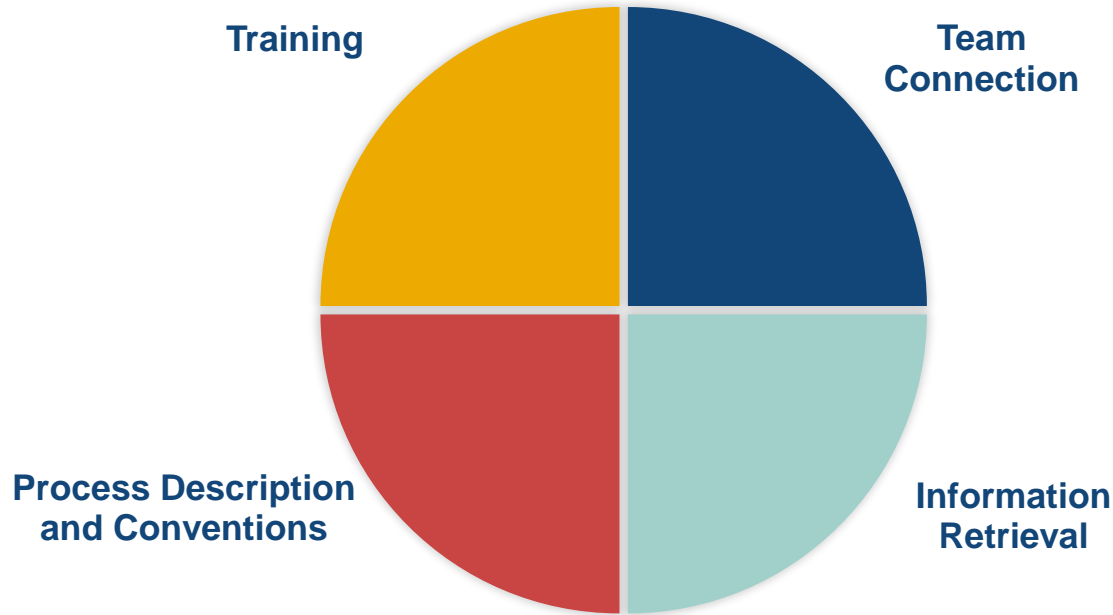


3. Project Evolution

Rules Development Team

Project Evolution

4 PROJECT PILLARS



Project Evolution

Team Connection



- Regular meetings in an informal setting
- Everybody can ask questions + learn from each other
- Keep everyone up-to-date on new decisions

Training



- Does everyone understand the process
- Repeat trainings on a regular basis for newcomers
- Workshops with F2F assistance

Project Evolution

Information Retrieval

Wiki Pages



- Conformance Rule Development Team
 - Decision Log
 - Executable Rule Authoring Processes
 - Training
 - Reference Guide**
 - Rule Type Templates
 - CORE Executable Status
 - Conformance Rule Development Team Meeting Notes
 - SDTMIG Conformance Rules Sign-up List**

GitHub allows better tracking of scripting updates

- Conformance Rules Editor
- Reference Guide
- Boolean Logic
- Check Operator
- Check Parameter
- Match Datasets (Merge)
- Operations (Aggregate)
- Rule Type
- Scope
- Sensitivity
- Metadata Variables
- Test Data
- Test Results
- Ticket Submission
- FAQ

Direct link: JIRA issue and Github ticket

JIRA tracker allows better follow-up of rule statuses

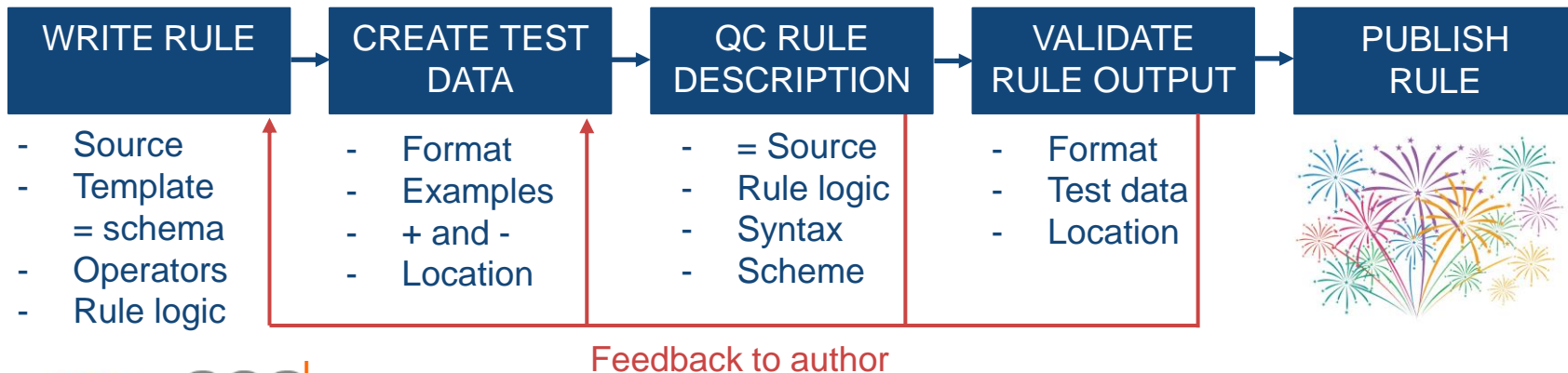
o	CORERULES-58	CG0034	Els Janssens	Dana Booth	?	PUBLISHED
o	CORERULES-65	CG0045	Els Janssens	Dana Booth	?	PUBLISHED
o	CORERULES-811	CG0049	Els Janssens	Amy Palmer	?	AUTHOR IN PROGRESS
o	CORERULES-1225	CG0049	Els Janssens	Amy Palmer	?	AUTHOR IN PROGRESS
o	CORERULES-829	CG0075	Els Janssens	Amy Palmer	?	AWAITING QC
o	CORERULES-1241	CG0075	Els Janssens	Amy Palmer	?	AWAITING QC
o	CORERULES-1287	CG0147	Els Janssens	Amy Palmer	?	AWAITING QC

Project Evolution

Process Description and Conventions



- Good documentation of the different steps:
 - Early day volunteers versus people joining later
 - Small group versus large group
 - Fixed workflow





4. HardCORE Practice

Develop and Validate Rules

HardCORE Practice

Source = SDTM and
SDTMIG Conformance
Rules v2.0

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule
CG0338	3.4	1	EVT	ALL	--SCAT		--SCAT != --DECOD

```
1 Check:
2   all:
3     - name: --SCAT
4       operator: equal_to_case_insensitive
5       value: --DECOD
6 Core:
7   Id: CORE-000195
8   Version: '1'
9   Status: Published
10  Description: Raise an error when --SCAT = --DECOD.
11  Outcome:
12    Message: --SCAT is equal to --DECOD.
13    Output Variables:
14      - --DECOD
15      - --SCAT
16  Rule Type: Record Data
17  Sensitivity: Record
18  Executability: Fully Executable
19  Authorities:
```

```
Scope:
Classes:
  Include:
    - EVENTS
Domains:
  Include:
    - ALL
```

- In Rule Editor via simple YAML syntax
- Written to output in case data is not conform the rule → detect errors in data
- Clear message to indicate what is incorrect in your data

HardCORE Practice

Source = SDTM and
SDTMIG Conformance
Rules v2.0

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule
CG0032	3.4	2	ALL	ALL	VISITDY	VISITNUM is in TV.VISITNUM	VISITDY = TV.VISITDY

```

1 Check:
2 all:
3   - name: VISITDY
4     operator: exists
5   - name: VISITNUM
6     operator: is_contained_by
7     value: $tv_visitnum
8   - name: VISITDY
9     operator: not_equal_to
10    value: TV.VISITDY
11 Match Datasets:
12 - name: TV
13   Keys:
14   - VISITNUM
15 Core:
16   Id: CORE-000249
17   Version: '1'
18   Status: Published
19 Description: Verify that visitdy is planned and exists in TV
20 Operations:
  
```

```

20 Operations:
21   - domain: TV
22     id: $tv_visitnum
23     name: VISITNUM
24     operator: distinct
25 Outcome:
26   Message: Visit Day cannot be found in Trial Visit (TV) domain
27   Output Variables:
28     - VISITDY
29     - VISITNUM
30 Rule Type: Record Data
31 Sensitivity: Record
  
```

```

1 Check:
2   Missing property "Executability". ya
3
  
```

Automatic
detection of errors

HardCORE Practice

Validation in Rule Editor

Does everything work?

EDIT TEST

- ✓ Validate YAML Syntax
- ✓ Validate YAML against Schema
- ✓ Convert YAML to JSON Rule
- ⌚ Load Test Data
- ⌚ Results

Loading test data

✓ Load Test Data

TEST DATASETS FILE...

Filename: unit-test-coreid-CG0513-negative 1.xlsx

Check output - expected?



Results

Negatives

4

Results

```
{ 1 item
  "DM": [ 1 item
    0: { 5 items
      "executionStatus": "success"
      "domain": "DM"
      "variables": [ 2 items
        0: "ACTARMCD"
        1: "ARMNRS"
      ]
      "message": "ACTARMCD is empty, but ARMNRS is not completed."
      "errors": [ 4 items
        0: { 3 items
          "value": { 2 items
            "ACTARMCD": ""
            "ARMNRS": ""
          }
          "row": 4
          "uSubjId": "CDISC004"
        }
      ]
    }
  ]
}
```



5. Key Learnings

Achievements & Challenges

Key Learnings

Achievements



- Rule writing and validation is easy and very accessible – no cold feet needed
- Only requirement is knowledge of the data standard - no programming
- Amazing work behind the scenes to translate simple rule code into complex scripts
- Hard work from project leads and volunteers



Challenges



- Impossible to foresee everything upfront – develop while doing - rework needed
- Will everyone do it correctly? - control
- Non-executable rules or ambiguous rules
- Keep info up to date and remove obsolete information – avoid confusion



6. Future Development

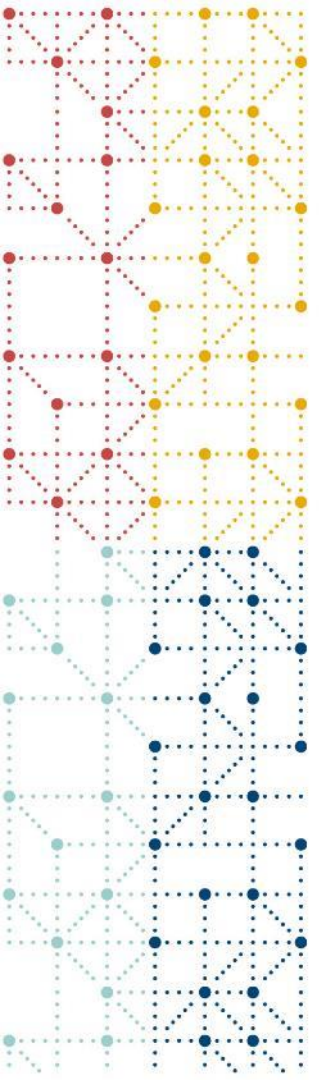
Future

Decisions to be made

- Use off-the-shelf validation systems
- Develop an in-house system
- New validation systems on the market?

What will other companies do?





CONCLUSION



**We took the decision to
jump...**

**It was the right decision,
we survived...**

**So there is no excuse to
not jump as well!**



Thank You!

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The logo for CDISC, featuring the word "cdisc" in a blue, lowercase, sans-serif font. Above the letters "i", "s", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "s", and a light blue dot above the "c".

The logo for SGS, featuring the letters "SGS" in a bold, grey, uppercase, sans-serif font. A vertical orange line is positioned to the right of the "S", and a horizontal orange line is positioned below the "S".