



2025

CDISC + TMF
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

From Silos to Synergy: Uniting Forces for a Successful CDISC Open Rules Implementation

Presented by Els Janssens and Marisa Wyckmans
Data Management System and Process Manager
SGS Pharma – Clinical Research

Meet the Speakers

Els Janssens

Title: DM System and Process Manager

Organization: SGS Pharma – Clinical Research

Els Janssens has 12+ years experience in Clinical Data Management. In her current role as Data Management System and Process Manager, she focuses on data standards and regulatory requirements and has an active role in the PHUSE EU Connect committee, CDISC E3C, and CDISC Open Rules.



Marisa Wyckmans

Title: DM System and Process Manager

Organization: SGS Pharma – Clinical Research

Marisa Wyckmans has 19 years experience in Clinical Data Management. In her current role as Data Management System 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

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



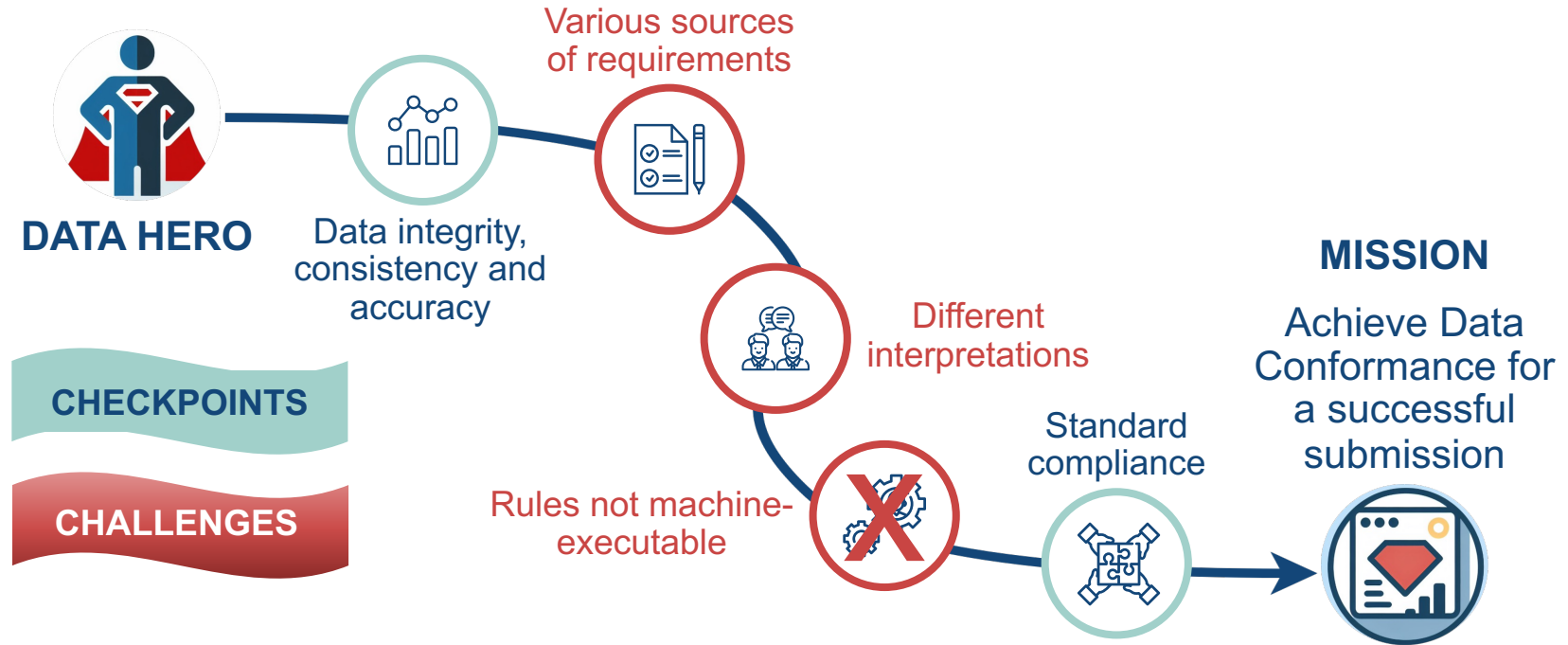
Agenda

1. Introduction
2. Project Goals and Scope
3. Implementation Journey and Success Stories
4. Strategies for Success
5. Key Takeaways



Introduction

Achieving Data Conformance: A Hero's Journey



CDISC Open Rules: A Hero's Sidekick



Executable Rules for each foundational standard

Compliance with CDISC and regulatory requirements

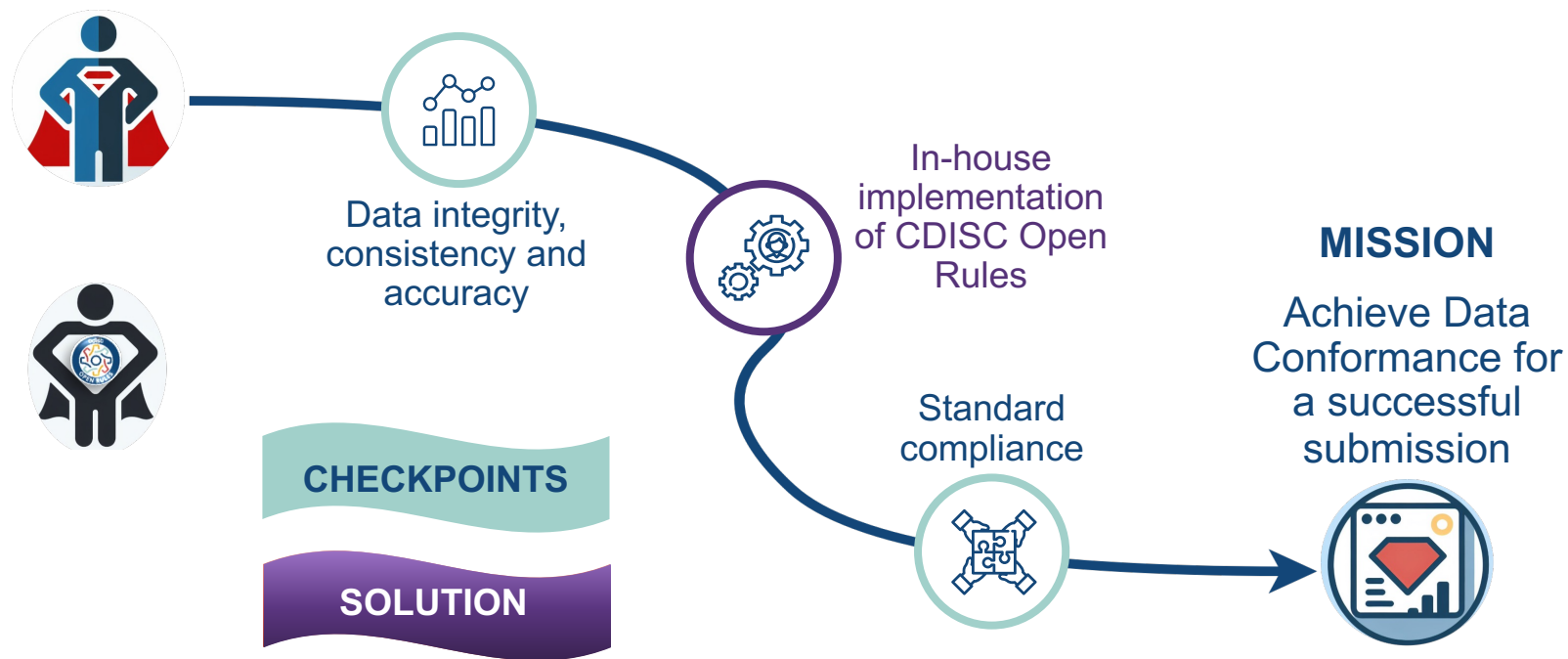


Unified Approach ensuring consistency and accuracy in submissions

Open-Source standard method for checking data conformance

Promising Prospect with an aligned vision and robust industry solution

CDISC Open Rules: Implementation



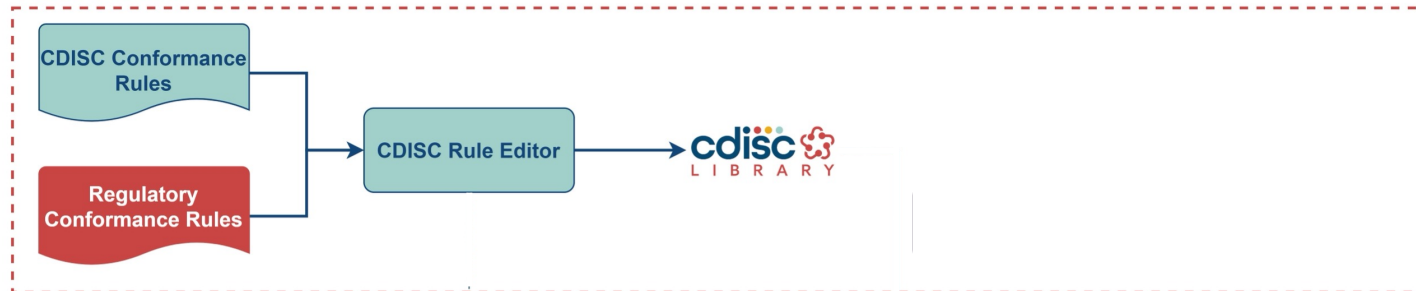


Project Goals and Scope

Project Goals: A Hero's Ambition



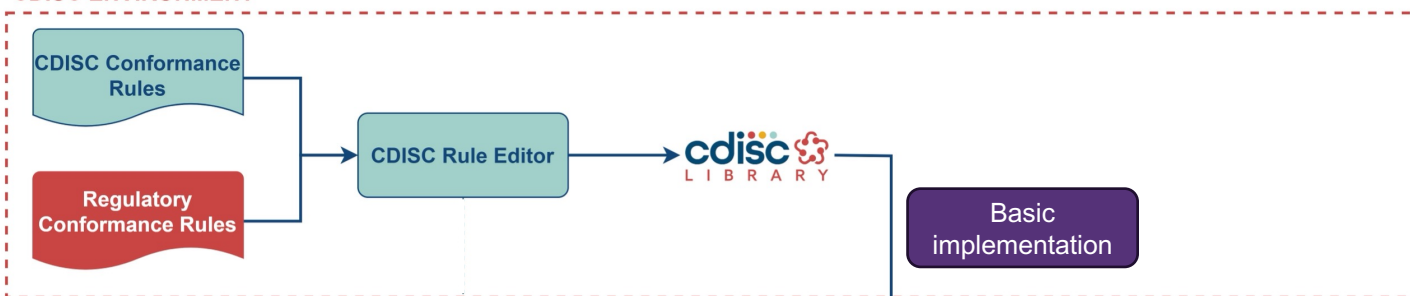
CDISC ENVIRONMENT



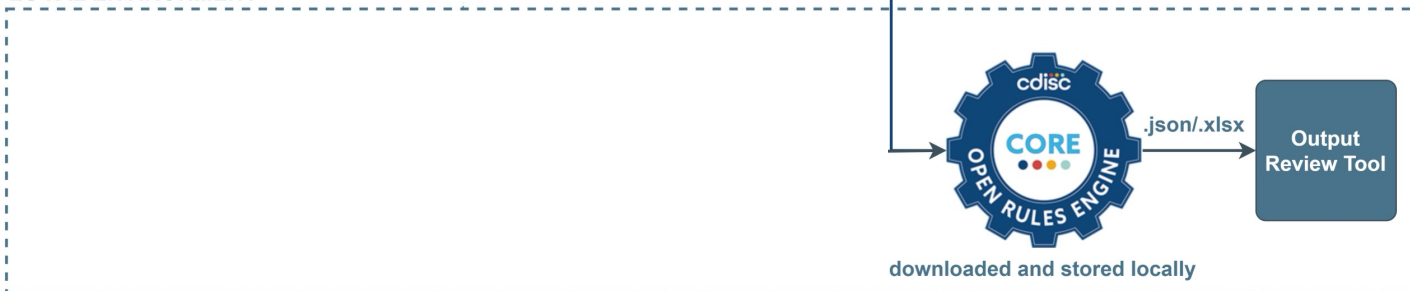
Project Goals: A Hero's Ambition



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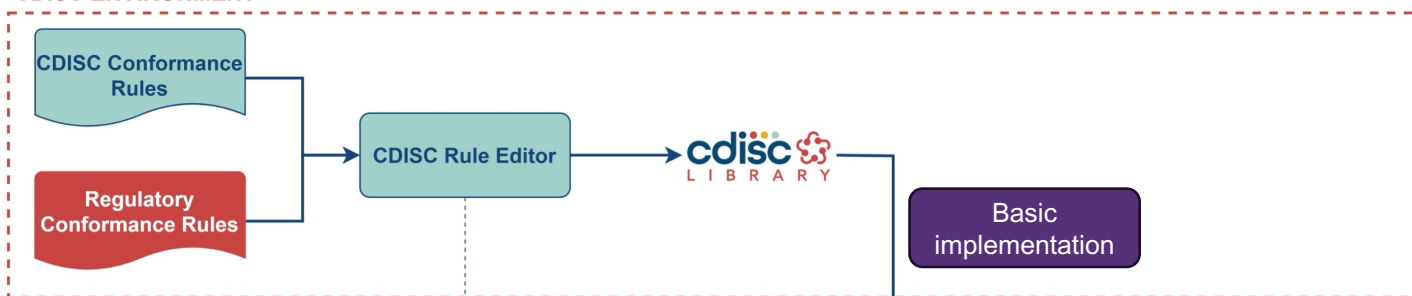
LOCAL ENVIRONMENT



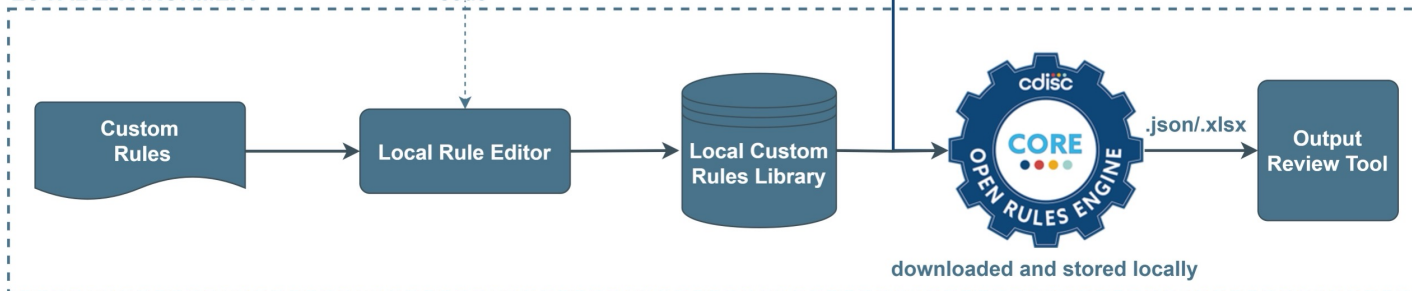
Project Goals: A Hero's Ambition



CDISC ENVIRONMENT



LOCAL ENVIRONMENT



local deployment of code

Basic implementation

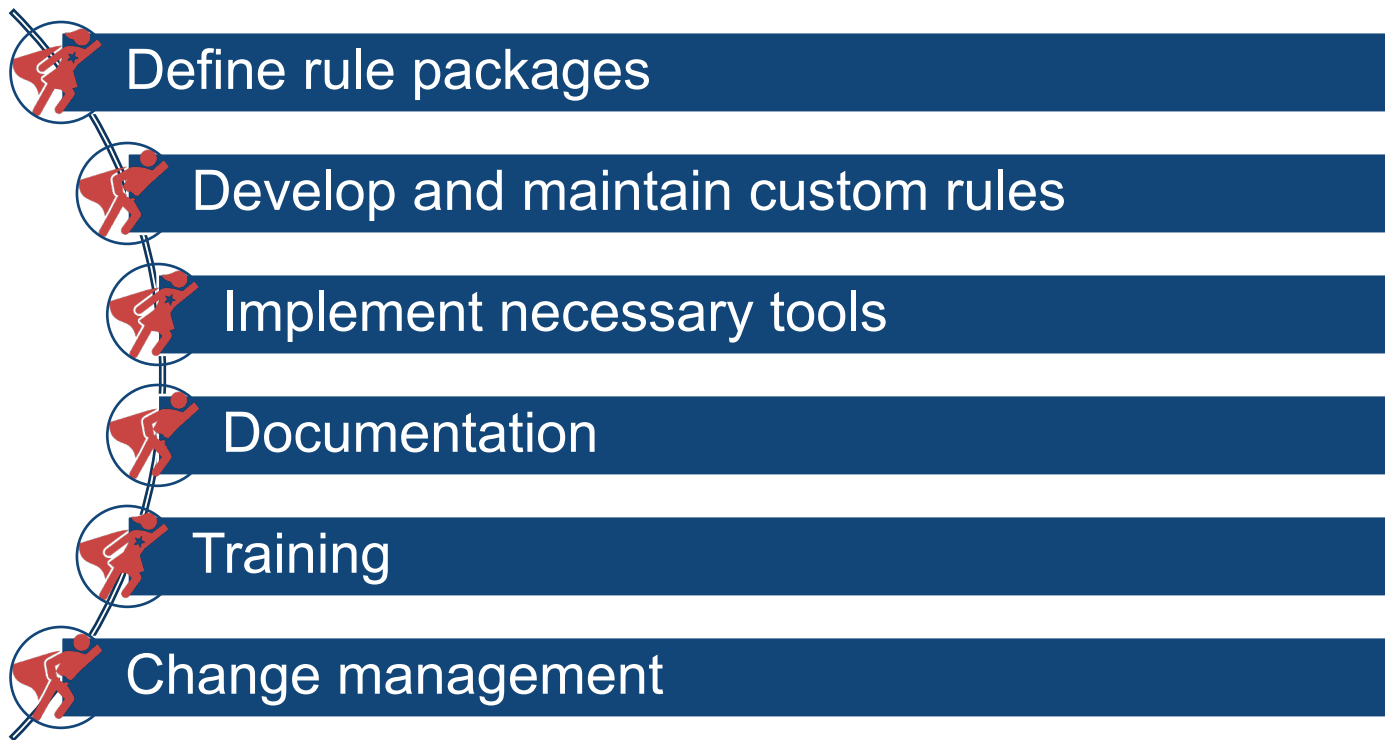
.json/.xlsx

Output Review Tool

Extended implementation

downloaded and stored locally

Project Scope: A Hero's Tasks

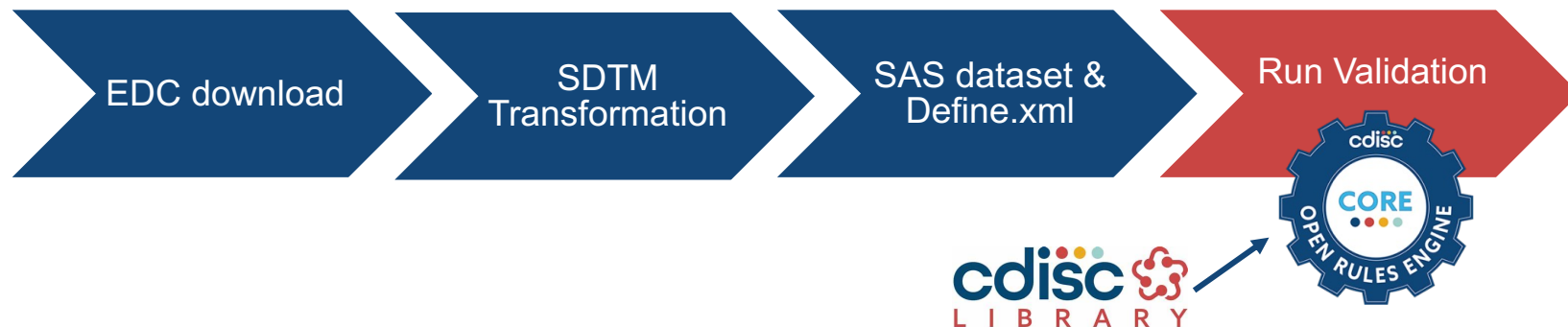




Implementation Journey & Success Stories

Implementation Journey: The Basics

Integrate CDISC Conformance rules into daily data validation process



- Proof of Concept successful
- Automated or ad hoc validation
- Await release CORE v1.0

Implementation Journey: The Extension

Create custom rules and integrate them into data validation process



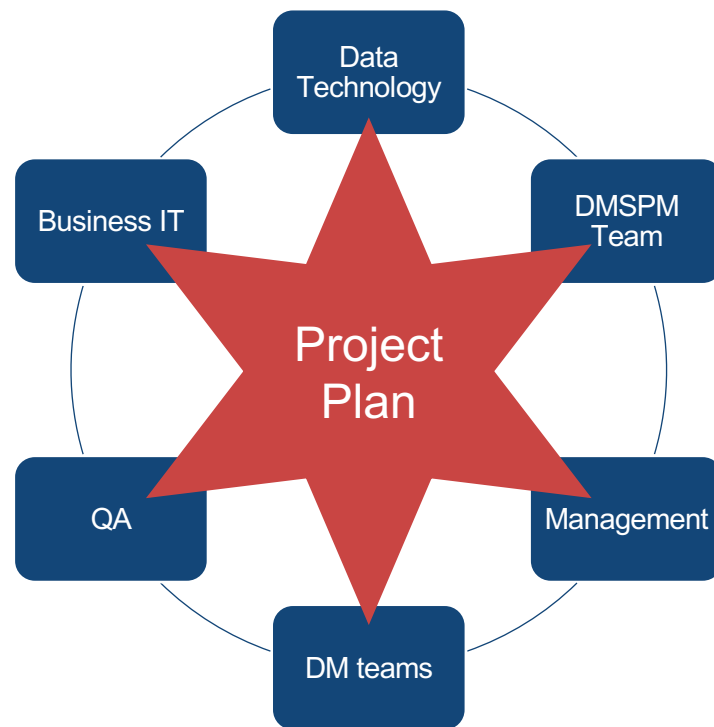
Proof of Concept successful

*Our Road to Adopting CORE: an Implementation Journey in SDTM Dataset Validation
(CDISC EU 2024, PHUSE EU Connect 2024)*

*Bending the Rules: A Deep Dive into Custom Rule Creation with the Open Rules Project
(CDISC US 2024)*

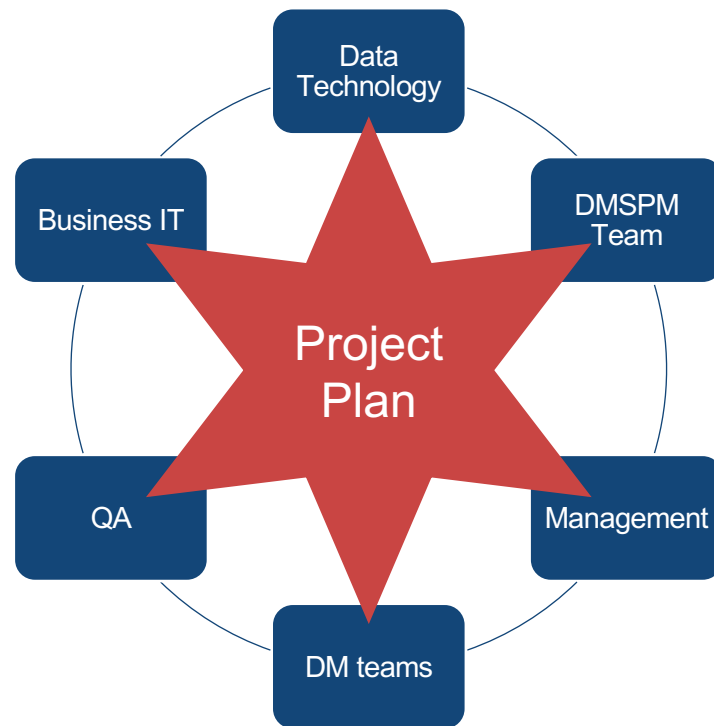
Implementation Journey: Advancing Together

- Rule packages
- Validated tools
 - Rule Editor
 - Rules Engine
 - User Interface to start ad hoc validation
- Standard processes
 - Rule governance
 - Rule storage and library maintenance
- Quality documentation
- Training



Implementation Journey: Advancing Together

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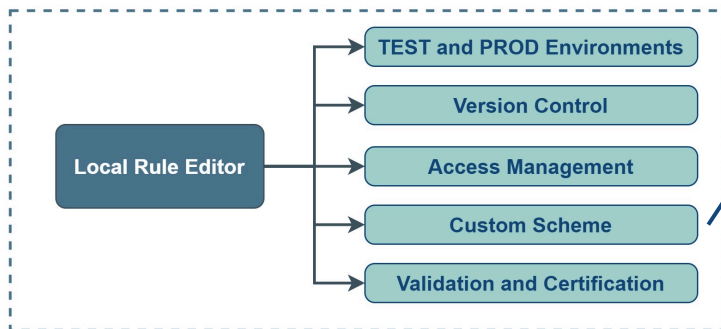
Implementation Journey: A Hero's Toolkit

WRITE

Rule Editor



PRIVATE CLOUD ENVIRONMENT



<

```
Authorities:
- Organization: "MyCompany"
  Standards:
  - Name: "Internal Standard"
    Version: "2.1"
  References:
  - Origin: "Internal Conformance Rules"
    Rule Identifier:
      Id: "INT001"
      Version: "1"
      Version: "1.0"
    Criteria:
      Type: "Success"
      Plain Language Expression: "Dataset must include a variable named STUDYID"

Category:
Sponsors:
- "Sponsor A"
- "Sponsor B"
Vendors:
- "CRO A"
- "Data Management B"
TherapeuticAreas:
- "Oncology"
- "Immunology"
Trials:
- "ONC-2025-01"
- "ONC-2025-02"
Purpose: "RAW data validation"
CompanyRuleLibrary: true
OutputType: "Check"
Keywords:
- "word1"
- "word2"
CustomAttribute: "This is a custom property"
```



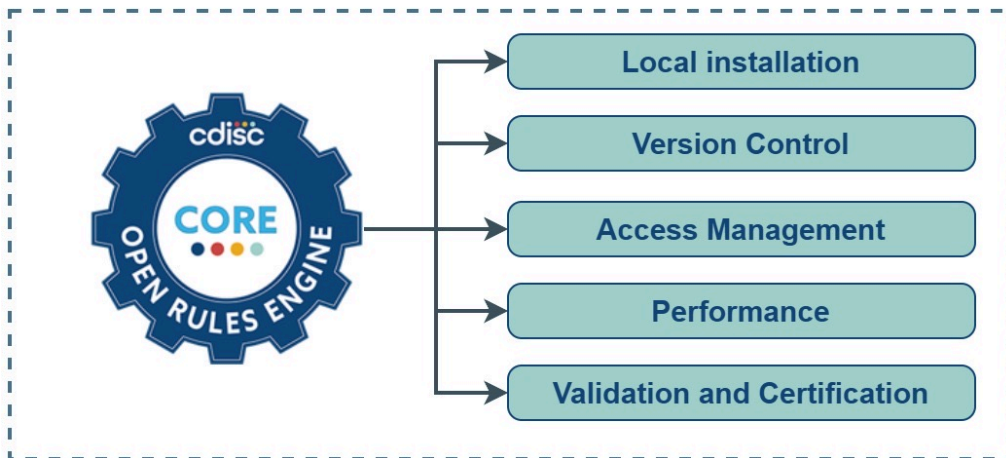
Implementation Journey: A Hero's Toolkit

VALIDATE

Rules Engine



LOCAL ENVIRONMENT



Implementation Journey: A Hero's Toolkit

VALIDATE

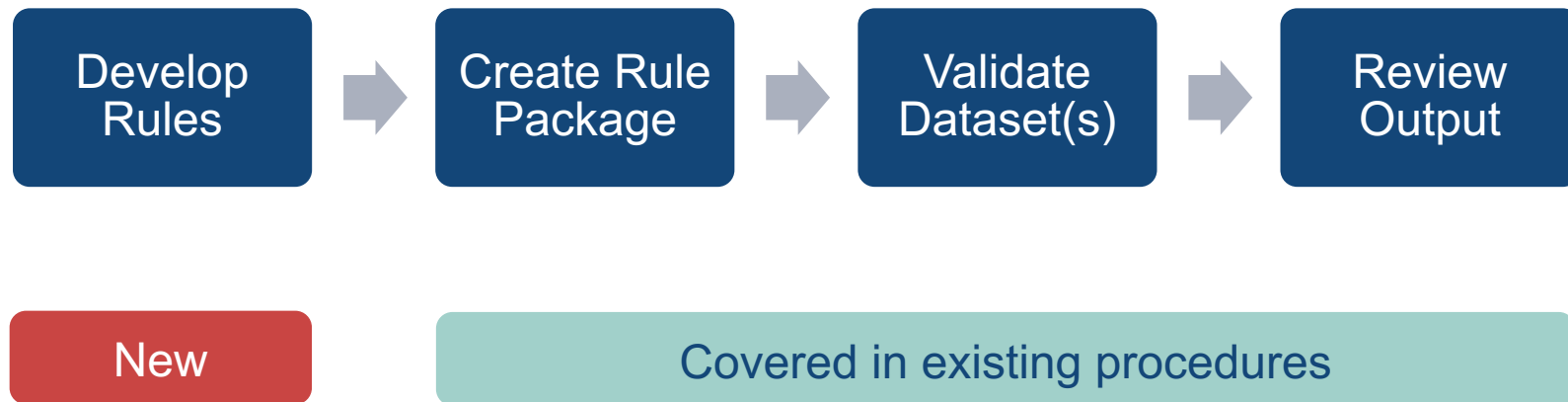
SGS CORE Validator



- User Interface to start ad-hoc validation
- Select parameters to initiate validation
- Access Management
- Validation and Certification

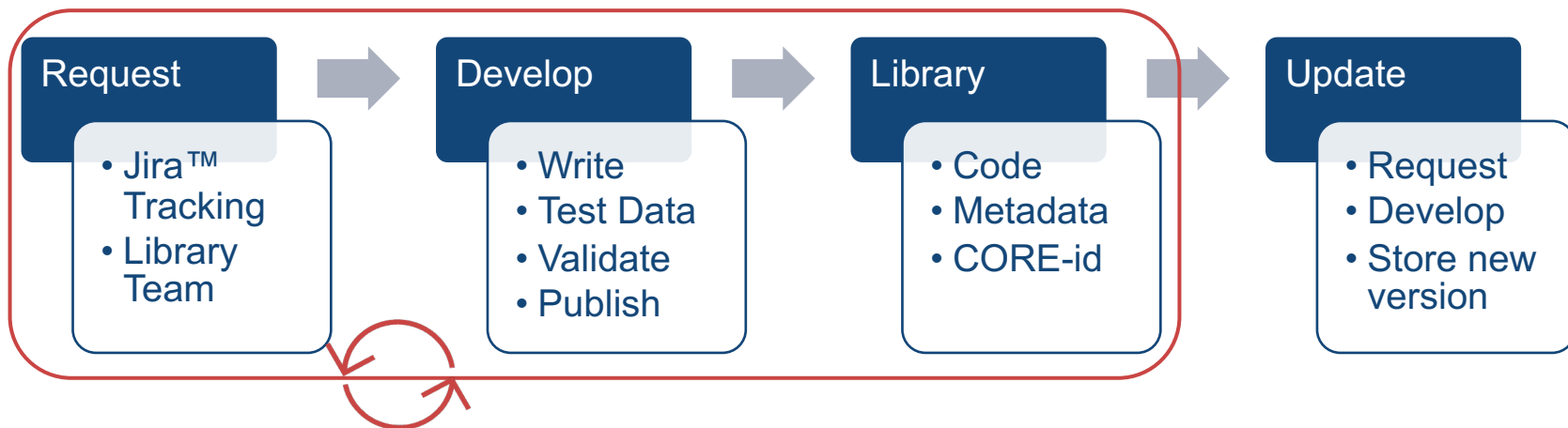
Implementation Journey: Standard Processes and Quality Documents

Gap Analysis



Implementation Journey: Standard Processes and Quality Documents

Custom Rule Governance, Storage and Maintenance

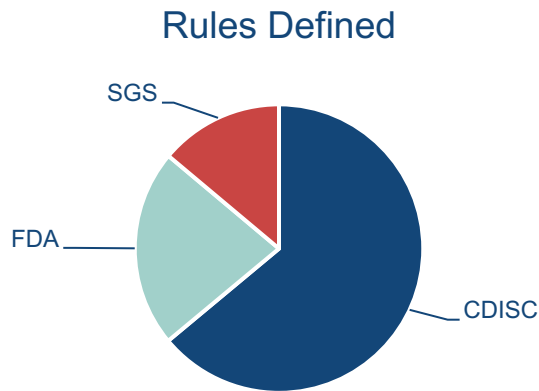


- Write new procedure on design of SGS CORE Library Rules
- SGS CORE Rule Naming Conventions



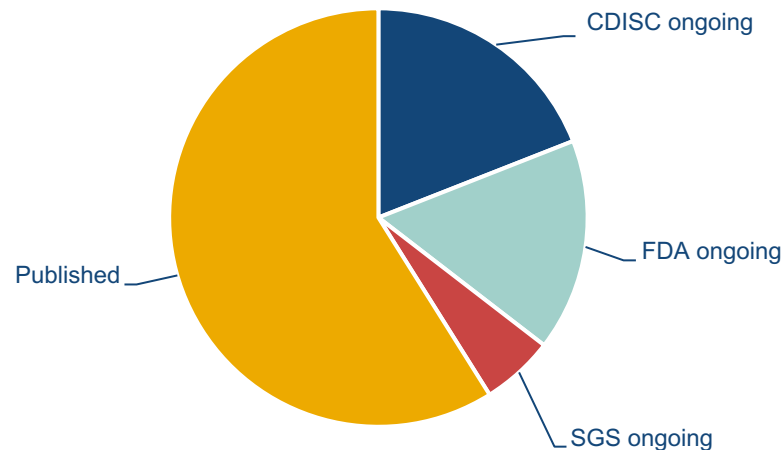
Success Stories: Rule Package – SDTM Conformance

Organization	Defined	Published	%
CDISC	534	375	70 %
FDA	185	48	26 %
SGS	116	69	59 %
Total	835	492	59 %



Rule Development Progress

Status 16/Apr/2025



Success Stories: Custom Rules on Non-SDTM Data

Check that **each variable in the transfer file** provided by the external party is specified in the Data Transfer Agreement (DTA).



DATA TRANSFER AGREEMENT

Transfer variable name	Transfer variable label	Format	Anticipated maximum length	Allowed values	Description of variable use
Study	Study Identifier	text	200	ABC	
Domain	Domain Abbreviation	text	200	PC	
Subject	Unique Subject Identifier	text	200		e.g. ABC-001
Test	Pharmacokinetic Test Short Name	text	8	Test 1, Test 2, Test 3	
Result	Result or Finding in Original Units	text	200		
Units	Original Units	text	200	ng/ml	

TRANSFER FILE

Study	File	Subject	Test	Result	Unit
Study Identifier	Domain Abbreviation	Unique Subject Identifier	Pharmacokinetic Test Short Name	Test Category	Result or Finding in Original Units
Char	Char	Char	Char	Char	Char
200	200	200	8	200	200
ABC	PC	ABC-001	Test1	5	ng/ml
ABC	PC	ABC-002	Test 2	10	ng/ml
ABC	PC	ABC-003	Test 3	20	ng/ml

Success Stories: Custom Rules on Non-SDTM Data

Check that each variable in the transfer file provided by the external party is specified in the Data Transfer Agreement (DTA).

RULE PROGRAMMING

```
Check:
  all:
    - name: variable_name
      operator: not_equal_to
      value: define_variable_name
Core:
  Status: Draft
  Version: '1'
Description: Check that each variable in the transfer file provided
by the external party is specified in the Data Transfer Agreement
(DTA).
Executability: Fully Executable
Outcome:
  Message: Variable in the transfer file is not specified in the DTA.
  Output Variables:
    - variable_name
Rule Type: Variable Metadata Check against Define XML
Scope:
  Classes:
    Include:
      - ALL
  Domains:
    Include:
      - ALL
Sensitivity: Record
```

OUTPUT RESULTS

```
{ 1 item
  "PC": [ 1 item
    { 6 items
      "executionStatus": "success"
      "dataset": "pc.xpt"
      "domain": "PC"
      "variables": [ 1 item
        { "variable_name"
        }
      ]
      "message":
        "Variable in the transfer file is not specified in the DTA."
      "errors": [ 2 items
        { 2 items
          { "value": { 1 item
              "variable_name": "File"
            }
          "row": 2
        }
        { 2 items
          { "value": { 1 item
              "variable_name": "Unit"
            }
          "row": 6
        }
      ]
    }
  ]
}
```



Strategies for Success



A Hero's Lessons Learned



Clear and Feasible Requirements

- **Listen** to needs and feasibility
- Define precise and achievable **goals**
- **Differentiate** between must-haves and nice-to-haves



Communication to Management

- Check-in on **vision** alignment
- Be **transparent** on achievements and hurdles
- Ask for **empowerment** when needed



Alignment with Goals and Plan

- Keep objectives and plans **in sync**
- Don't overcomplicate **documentation**
- Provide **access** to Project Plan



A Hero's Lessons Learned



Good Teamwork

- Include **liaisons** between tech and non-tech
- Regular **meetings** to exchange work and ideas
- Look **across** the department for ideas and expertise



Involve All Stakeholders Early

- **Communicate** plans
- Don't forget impact on **quality and data protection**
- Gather **feedback** regularly



Open Dialogue with CDISC

- **Communicate** needs and reason
- Provide **input and feedback** on development
- Discuss implementation issues **together**



Key Takeaways

Key Takeaways

Added Value

Implementing CDISC Open Rules in-house enhances data quality, compliance, and efficiency

Worth the Effort

Although challenging, the integration of CDISC Open Rules is a valuable investment for streamlined validation processes

Collaboration is Key

Effective internal communication and collaboration with CDISC are crucial for successful implementation



DATA HERO



DATA HERO TEAM

Thank You!

Contact us



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www.sgs.com/pharma



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