# Pimp Your Data Validation with CDISC Open Rules Health Inspired, Quality Driven.

Els Janssens | SGS Pharma Clinical Research, Mechelen, Belgium

#### Introduction

Achieving data conformance is essential for ensuring the integrity, consistency, and accuracy of clinical data packages and involves adhering to standards and regulatory requirements. However, challenges arise in achieving data conformance due to the presence of numerous sources, varied interpretations, and non-executable conformance rules.

### CDISC Open Rules Project<sup>1</sup>: Ensuring Data Conformance



- Executable Rules for each foundational standard
- Compliance with CDISC and regulatory requirements
- Unified Approach ensuring consistency and accuracy in submissions



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	na/ml	

- Open-Source standard method for checking data conformance
- Promising Prospect with an aligned vision and robust industry solution

## Effective In-house Implementation Strategies for Data Validation

#### **BASIC IMPLEMENTATION**

Retrieve CDISC-governed rules from the CDISC Library and integrate into daily data validation process.

#### EXTENDED IMPLEMENTATION

Create custom rules to enhance and extend standard conformance rules and integrate these into data validation processes.



Figure 1: Schematic overview of the in-house implementation strategy for CDISC Open Rules. This strategy allows for the integration of both CDISC-governed rules and custom rules into the data validation process.

## **Advanced Custom Rule Solutions**

The CDISC Rule Editor and Open Rules Engine, offer a custom schema that enables the creation of various types of custom rules:

- SDTM Rules: Address additional SDTM conformance
- Data Cleaning Rules: Ensure accuracy of data content
- External Data Rules: Validate non-SDTM data





**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
BC	PC	ABC-001	Test1	5	ng/m
BC	PC	ABC-002	Test 2	10	ng/m
BC	PC	ABC-003	Test 3	20	ng/m
					-

#### **RULE PROGRAMMING**

RULE PROGRAMMING	OUTPUT RESULTS		
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	<pre> { 1 item     "PC" : [ 1 item     " 0 : { 6 items     "executionStatus" : "success"     "dataset" : "pc.xpt"     "domain" : "PC"     " variables" : [ 1 item         0 : "variable_name"     ]     "message" :     "Variable in the transfer file is not specified in the DTA."     " "errors" : [ 2 items</pre>		

Figure 3: Example of custom rule creation for external data in a non-SDTM format

## **Groundbreaking Benefits**

#### STANDARDIZATION

- Enhanced rule creation and direct access to new CDISC rules
- Improved industry-wide data validation

#### TRANSPARENCY

- CDISC interpretation and programming logic freely available
- Single source of truth for the industry

#### COLLABORATION

- Improved stakeholder collaboration
- Custom rule exchange via open-source method

## Conclusion

The CDISC Open Rules Project ensures consistent and accurate submissions through a unified, open-source approach. It offers solutions for effective in-house implementation, from retrieving CDISC-governed rules to creating and integrating custom rules.

Join us in adopting CDISC Open Rules. Together, we can achieve higher standards

Figure 2: A fixed CDISC schema is used for creation of CDISC and regulatory-defined conformance rules. Custom schema, with required and adaptable elements, allows companies to create custom rules with custom metadata. and drive industry innovation.

#### REFERENCES

CDISC Open Rules Project: https://www.cdisc.org/core1

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## Contact us

in sgs.com/linkedinpharma ⊠ clinicalresearch@sgs.com

#### sgs.com/pharma





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