PP06

Pimp Your Data Validation with CDISC Open Rules

Health Inspired, Quality Driven.

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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[1]: Ensuring Data Conformance

- 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

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.

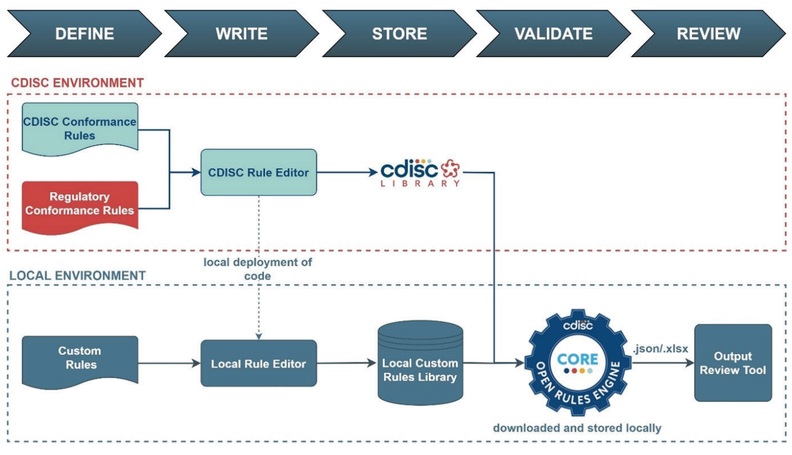

Figure 1: Schematic overview of the in-house implementation strategy for CDISC Open Rules. This strategy allows for the integration of both CDISC-governed rules and custom rules into the data validation process.

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

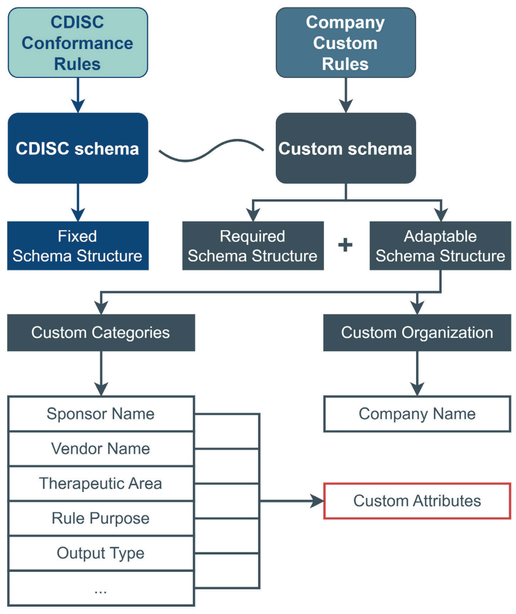

Figure 2: A fixed CDISC schema is used for creation of CDISC and regulatory-defined conformance rules. Custom schema, with required and adaptable elements, allows companies to create custom rules with custom metadata.

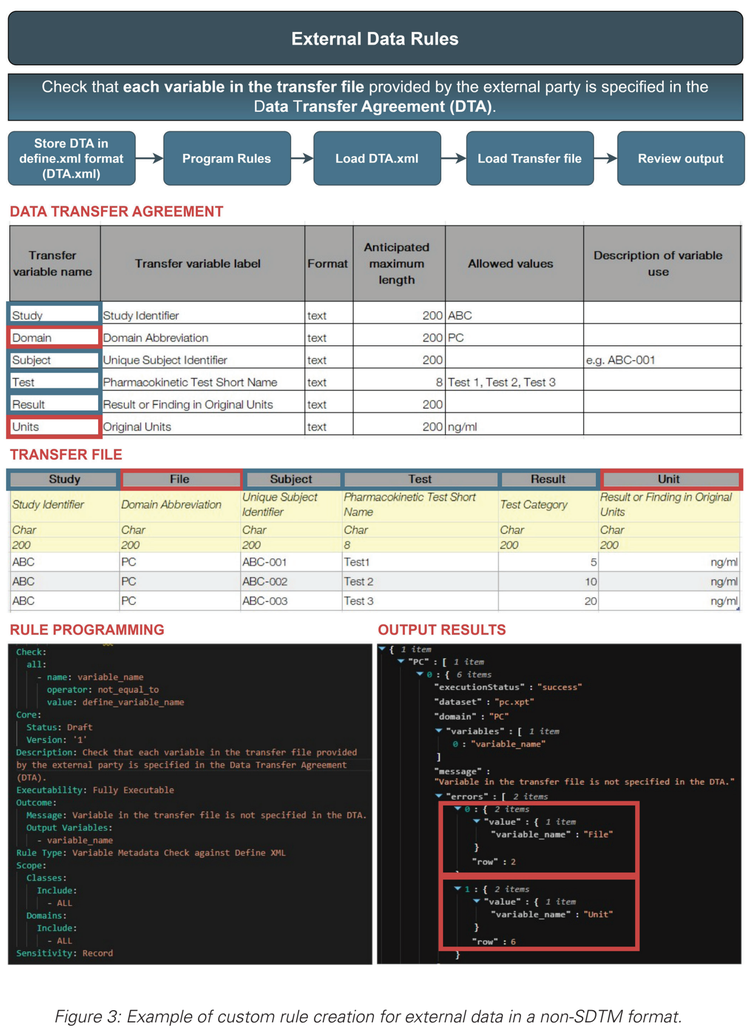

Figure 3: Example of custom rule creation for external data in a non-SDTM format.

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 and drive industry innovation.

REFERENCES

CDISC Open Rules Project: https://www.cdisc.org/core[1]

ACKNOWLEDGEMENTS

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