



From Standards to Strategy: Customizing CDISC Open Rules for TMF Reference Model

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Agenda

- Background: CDISC Open Rules Engine (CORE)
- Motivation for Extension
- CORE as a solution
- How?
- Key benefits
- Strategic Impact
- Key Takeaways

Background: CDISC Open Rules Engine (CORE)

- Open-source, rule-based dataset validation (SDTM, ADaM)
- Generates conformance reports to support data quality and regulatory compliance
- Initial focus on clinical dataset validation
- Flexible architecture for broader clinical applications

Motivation for Extension

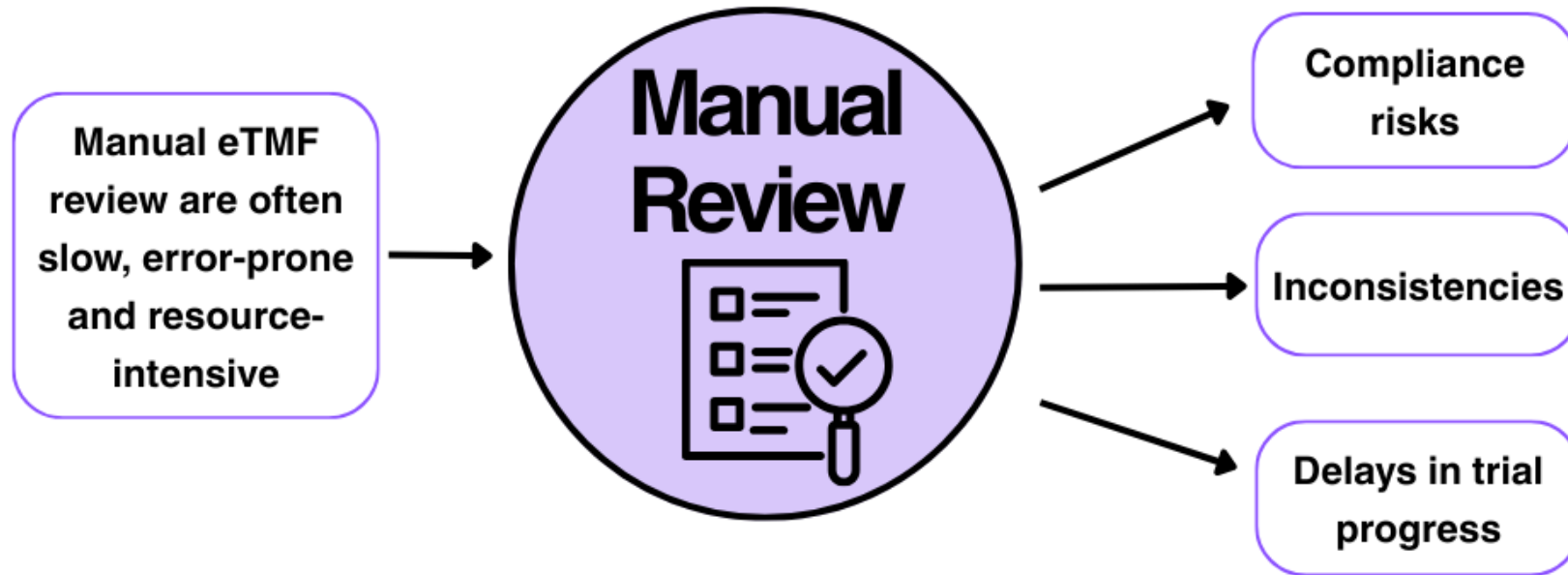
- CORE can be extended to support a variety of areas beyond data standards, including electronic Trial Master File (eTMF), Medical Data Review, and Bioresearch Monitoring (BIMO).

But why extend?

- eTMF is critical for GCP and regulatory compliance
- eTMF quality reviews often carried out manually, typically through periodic checks performed by several stakeholders responsible for different sections

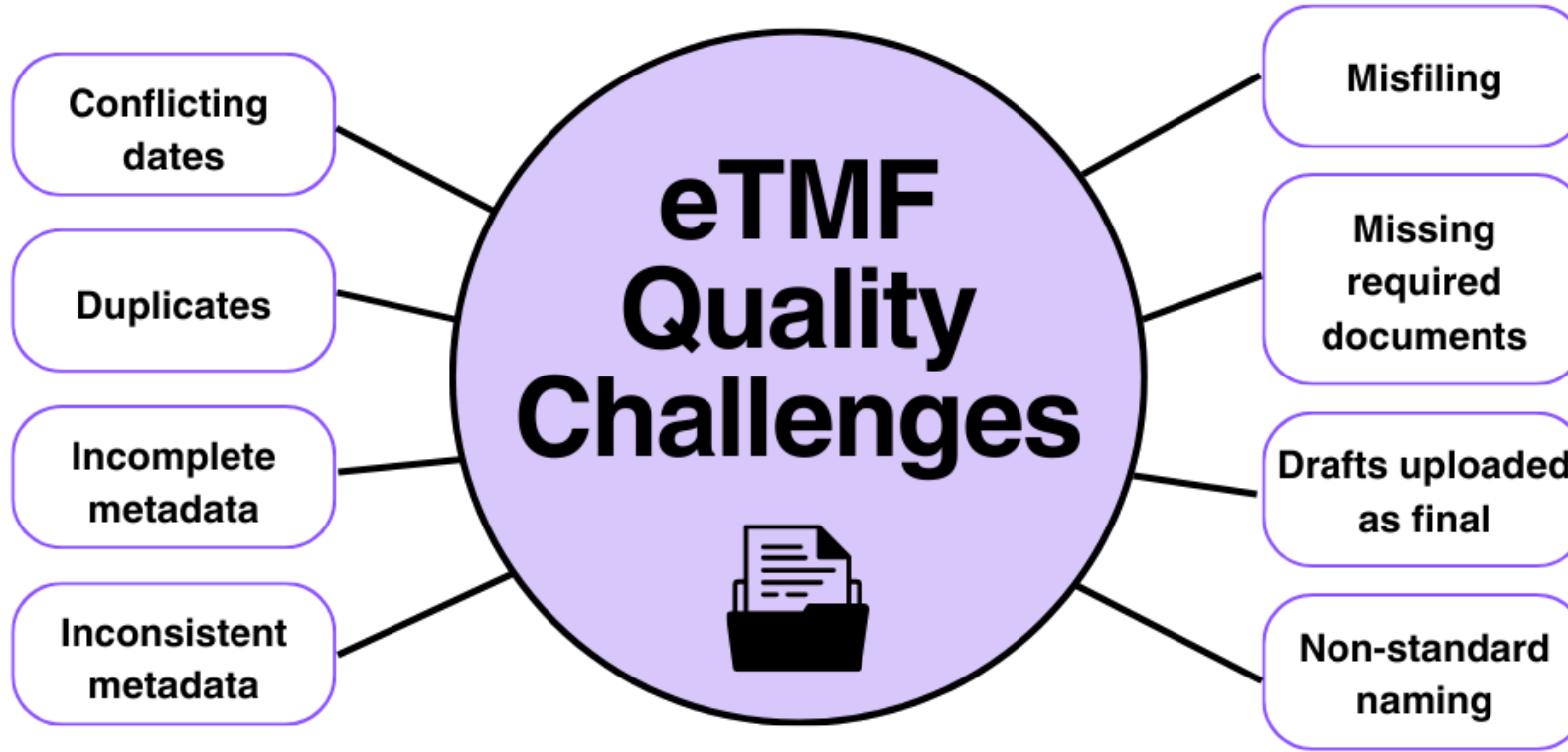


Motivation for Extension



➡ **Need for automation** 

Motivation for Extension



These types of errors, while often minor on their own, can accumulate over time and undermine the integrity of the entire eTMF

CORE as a solution

- Addresses the eTMF-specific challenges
- Can perform consistent, comprehensive, and repeatable quality checks across the entire eTMF structure
- Maps TMF Reference Model requirements to rule logic
- Delivers strategic quality oversight
- Is a customizable solution for maintaining documentation quality and readiness across the trial lifecycle

How - Input

- eTMF metadata extraction

The screenshot displays the 'TMF Viewer' interface. At the top, a navigation bar includes links for Home, Study Info, Planning, Library, TMF Homepage, TMF Viewer (active), Reports, and Archive. Below this is a breadcrumb trail with fields for 'Select Study Country' and 'Select Site'. The left sidebar shows a tree view under 'TMF RM v3.0' with categories like 'All Documents', '01 Trial Management', '02 Central Trial Documents', '03 Regulatory', '05 Site Management', and '06 IP and Trial Supplies'. The main area features a search bar and a table with columns: Name, Version, Additional Information, Document Date, and a filter icon. The table lists two documents with versions 0.1 and 1.0. A context menu is open over the table, offering 'EXPORT' options (CSV, Excel) and 'VIEW' options (Edit columns, Truncate Cell Text). Pagination at the top right indicates '1-25 of 259' items, with page '1' of '11' displayed.

Name	Version	Additional Information	Document Date
▶ [Icon]	0.1		
▶ [Icon]	1.0		

How - Input

- Extraction is structured in an excel workbook with 4 tabs

[illegible]

How - Input

STUDYID	ETMFTREE
Study Identifier	eTMF Tree Structure
Char	Char
9	200
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.01 Trial Master File Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.02 Trial Management Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.03 Quality Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.04 List of SOPs Current During Trial
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.05 Operational Procedure Manual
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.06 Recruitment Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.07 Communication Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.08 Monitoring Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.09 Medical Monitoring Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.10 Publication Policy
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.11 Debarment Statement
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.12 Trial Status Report
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.13 Investigator Newsletter
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.14 Audit Certificate
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.15 Filenote Master List
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.16 Risk Management Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.17 Vendor Management Plan
STUDY-001	Study\01 Trial Management\01.01 Trial Oversight\01.01.18 Roles and Responsibility Matrix

How - YAML

Rules are written in
YAML Code.

Rules can be
customized by adding
sponsor-specific details
to the general rule set.

```
1 Authorities:
2   - Organization: Enovalife
3     Standards:
4       - Name: eTMF
5         References:
6           - Citations:
7             - Cited Guidance: The version of the document should be completed
8               Document: ''
9               Item: ''
10              Section: ''
11          Criteria:
12            Logical Expression:
13              Condition: ''
14              Rule: ''
15            Plain Language Expression: ''
16            Type: 'Success'
17            Origin: 'IHB'
18            Release Notes: ''
19            Rule Identifier:
20              Id: 'ETMF0003'
21              Version: '1'
22            Validator Rule Message: ''
23            Version: ''
24            Version: '3.3.1'
25 Check:
26   all:
27     - name: DOCVERSN
28       operator: empty
29 Core:
30   Id: BDLS-000010
31   Status: Published
32   Version: '1'
33 Description: 'The version of the document should be completed'
34 Executability: Fully Executable
35 Outcome:
36   Message: 'The version of the document should be completed'
37   Output Variables:
38     - DOCVERSN
39 Rule Type: Record Data
40 Scope:
41   Classes:
42     Include:
43       - ALL
44   Domains:
45     Include:
46       - ALL
47 Sensitivity: Record
```

How – Validator

The published rules are visible in the UI where you can create your own rule set.

You choose the data batch and datasets on which the validation needs to occur and select your rule set.

The screenshot displays the 'Conformance Validator' web application. The top navigation bar includes a logo, a user profile 'Ibbe Borghijs', and a progress indicator with three steps: 'Choose your Data Batch', 'Choose your Datasets', and 'Configure your Conformance Rules' (the current step). Below the progress bar, there are dropdown menus for 'Data Model' (eTMF), 'Model IG Version' (3.3.1), and 'Publisher' (Enovalife), along with buttons for 'Local Rules', 'Dictionaries', and 'Save Ruleset'. The main content area is titled 'Conformance Rules' and features a search bar and a 'My Rule Sets' dropdown. A table lists 11 rules, each with a checkbox, a rule ID, a rule type, a description, a version, and a severity level (all marked as 'Error'). The table is scrollable, and the bottom of the page shows pagination controls (1 / 1) and a 'Show lines: 10' dropdown.

☐	Rule ID ↑	Rule Type	Description	Version	Rule Severity
☐	ETMF0001	Value Uniqueness	Document ID should be unique throughout the whole Study eTMF	1.0	Error
☐	ETMF0002	Model Deviation	The document path should match the expected tree structure	1.0	Error
☐	ETMF0003	Value Presence	The version of the document should be completed	1.0	Error
☐	ETMF0004	Value Presence	The date of the document should be completed	1.0	Error
☐	ETMF0005	Model Deviation	The name of the document does not follow the naming convention based on the artifact name	1.0	Error
☐	ETMF0007	Value Consistency	The folder is empty but should have been completed as per TMF index.	1.0	Error
☐	ETMF0008	Value Consistency	The folder is not empty but should not have been completed as per TMF index.	1.0	Error
☐	ETMF0009	Value Consistency	Document date in the Document Title should match the Document Date from metadata	1.0	Error
☐	ETMF0010	Value Consistency	Document version in the Document Title should match the Document version from metadata	1.0	Error
☐	ETMF0011	Model Deviation	The document version in the metadata should be numeric	1.0	Error

How - Output

After validation, an output is generated by the engine and is available in UI. It can be also downloaded as an Excel file.

All Studies
Home > My Studies > Study003 > Report >
Study003 - ISSUES - 2025-09-24T14:58:57 > Issue Summary

[Download Report](#)

Study003 - Issues | **Issue Summary** | Issue Details | Rules Report

Search...

Dataset	Rule ID	Error message	Severity	# Issues	Explanation
METADATA	ETMF0002	The document path should match the expected tree structure	Error	1	
METADATA	ETMF0003	The version of the document should be completed	Error	2	
METADATA	ETMF0004	The date of the document should be completed	Error	2	
METADATA	ETMF0005	The name of the document does not follow the naming convention based on the artifact name	Error	1	
METADATA	ETMF0009	Document date in the Document Title should match the Document Date from metadata	Error	3	
METADATA	ETMF0010	Document version in the Document Title should match the Document version from metadata	Error	2	
METADATA	ETMF0011	The document version in the metadata should be numeric	Error	4	
METADATA	ETMF0013	The document status should be final	Error	3	
METADATA	ETMF0014	Document Type does not match correct document index	Error	1	

Total issues: 19

Show lines: 10

How - Output



All Studies

Home > My Studies > Study003 > Report >
Study003 - ISSUES - 2025-09-24T14:58:57 > Issue Details



Study003 - Issues

Issue Summary

Issue Details

Rules Report

Search...

Rule ID	Error message	Severity	Dataset	USUBJID	Record	Sequence	Variables	Values
ETMF0003	The version of the document should be completed	Error	METADATA		731		DOCVERSN	null
ETMF0003	The version of the document should be completed	Error	METADATA		2003		DOCVERSN	null
ETMF0004	The date of the document should be completed	Error	METADATA		731		DOCDAT	null
ETMF0004	The date of the document should be completed	Error	METADATA		2003		DOCDAT	null
ETMF0011	The document version in the metadata should be numeric	Error	METADATA		1242		DOCVERSN	v1.0
ETMF0011	The document version in the metadata should be numeric	Error	METADATA		1243		DOCVERSN	v2.0
ETMF0011	The document version in the metadata should be numeric	Error	METADATA		1244		DOCVERSN	v3.0
ETMF0011	The document version in the metadata should be numeric	Error	METADATA		1245		DOCVERSN	v4.0
ETMF0013	The document status should be final	Error	METADATA		114		DOCSTAT	Draft
ETMF0013	The document status should be final	Error	METADATA		242		DOCSTAT	Draft

Total issues: 19

Show lines: 10

How - Output

All Studies
Home > My Studies > Study003 > Report >
Study003 - ISSUES - 2025-09-24T14:58:57 > Rules report

[Download Report](#)

Study003 - Issues | Issue Summary | Issue Details | **Rules Report**

Search...

Rule ID ↓	Version	Error message	Severity	Status
ETMF0001	1.0	Document ID should be unique throughout the whole Study eTMF	Reject	Success
ETMF0002	1.0	The document path should match the expected tree structure	Error	Success
ETMF0003	1.0	The version of the document should be completed	Error	Success
ETMF0004	1.0	The date of the document should be completed	Error	Success
ETMF0005	1.0	The name of the document does not follow the naming convention based on the artifact name	Error	Success
ETMF0007	1.0	The folder is empty but should have been completed as per TMF index.	Error	Success
ETMF0008	1.0	The folder is not empty but should not have been completed as per TMF index.	Error	Success
ETMF0009	1.0	Document date in the Document Title should match the Document Date from metadata	Error	Success
ETMF0010	1.0	Document version in the Document Title should match the Document version from metadata	Error	Success
ETMF0011	1.0	The document version in the metadata should be numeric	Error	Success

Show lines: 10

How - Output

- Output Can also be generated as an Excel File

	A	B	C	D	E	F	G	H	
1	Rule ID	Error Message	Severity	Dataset	USUBJID	Record	Sequence	Variables	Values
2	ETMF0003	The version of the document should be completed	Error	METADATA		731		DOCVERSN	null
3	ETMF0003	The version of the document should be completed	Error	METADATA		2003		DOCVERSN	null
19									
20									
21									
22									
23									
24									
25									
26									

Key Benefits

- Timeliness
- Efficiency
- Standardization
- Error Reduction
- Cost Reduction
- Customization

Strategic Impact

- Delivers strategic quality oversight
- Shift from reactive corrections to proactive quality management

Key Takeaways

- Technology as a partner for trial success
- Continuous, integrated process
- Enhances operational efficiency and regulatory excellence

Thank you for your attention!

Your point of contact

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