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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

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

Irina Sargsyan, Head of Biometrics, Enovalife

Speakers

Irina Sargsyan
Head of Biometrics
Enovalife

- Irina brings nearly 20 years of experience in clinical research, spanning data management, standards implementation, and biometrics leadership.
- She began her career as a Clinical Data Manager and then played an active role in CDISC standardization projects before moving into project management, where she gained extensive experience across biometrics operations.
- For the past six years, Irina has led the biometrics team at Enovalife.

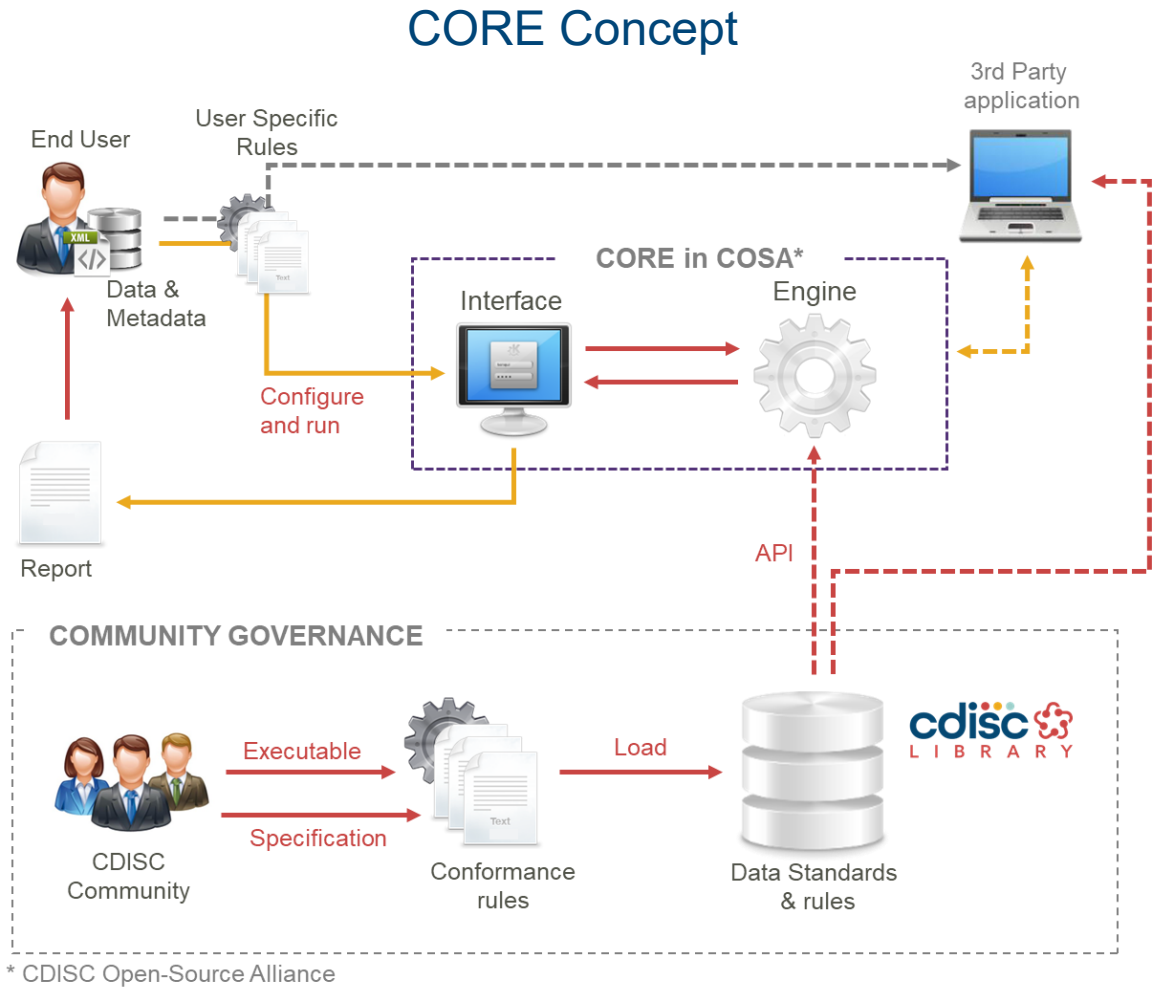
Agenda

1. Background & Motivation for Extension
2. CORE as a solution
3. Exploring Validation eTMF - How to….
4. Conclusion - Key Benefits & Strategic Impact

Motivation for Extension

Background & Motivation for Extension

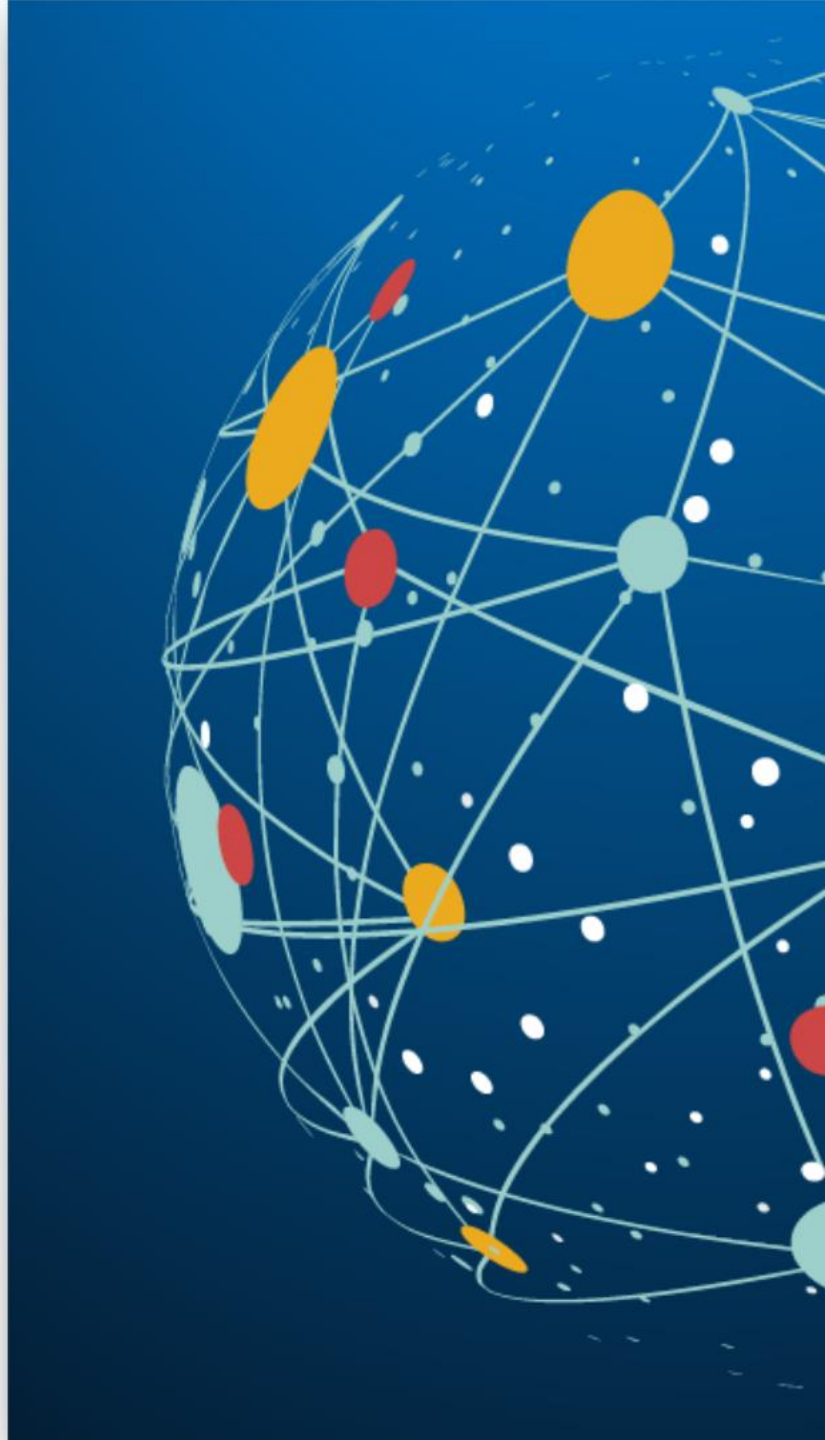
- CDISC Open Rules Engine (CORE)
  - Open-source, rule-based dataset validation (SDTM, ADaM)
  - Generates conformance reports to support data quality and regulatory compliance
  - Initial focus on clinical datasets validation
  - Flexible architecture for broader clinical applications



Background & Motivation for Extension

- CORE can be extended to support quality control of:
  - electronic Trial Master File (eTMF)
  - Medical Review
  - 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



Background & Motivation for Extension

Manual eTMF review are often slow, error-prone and resource-intensive

- Compliance risks
- Inconsistencies
- Delays in trial progress

Need for automation

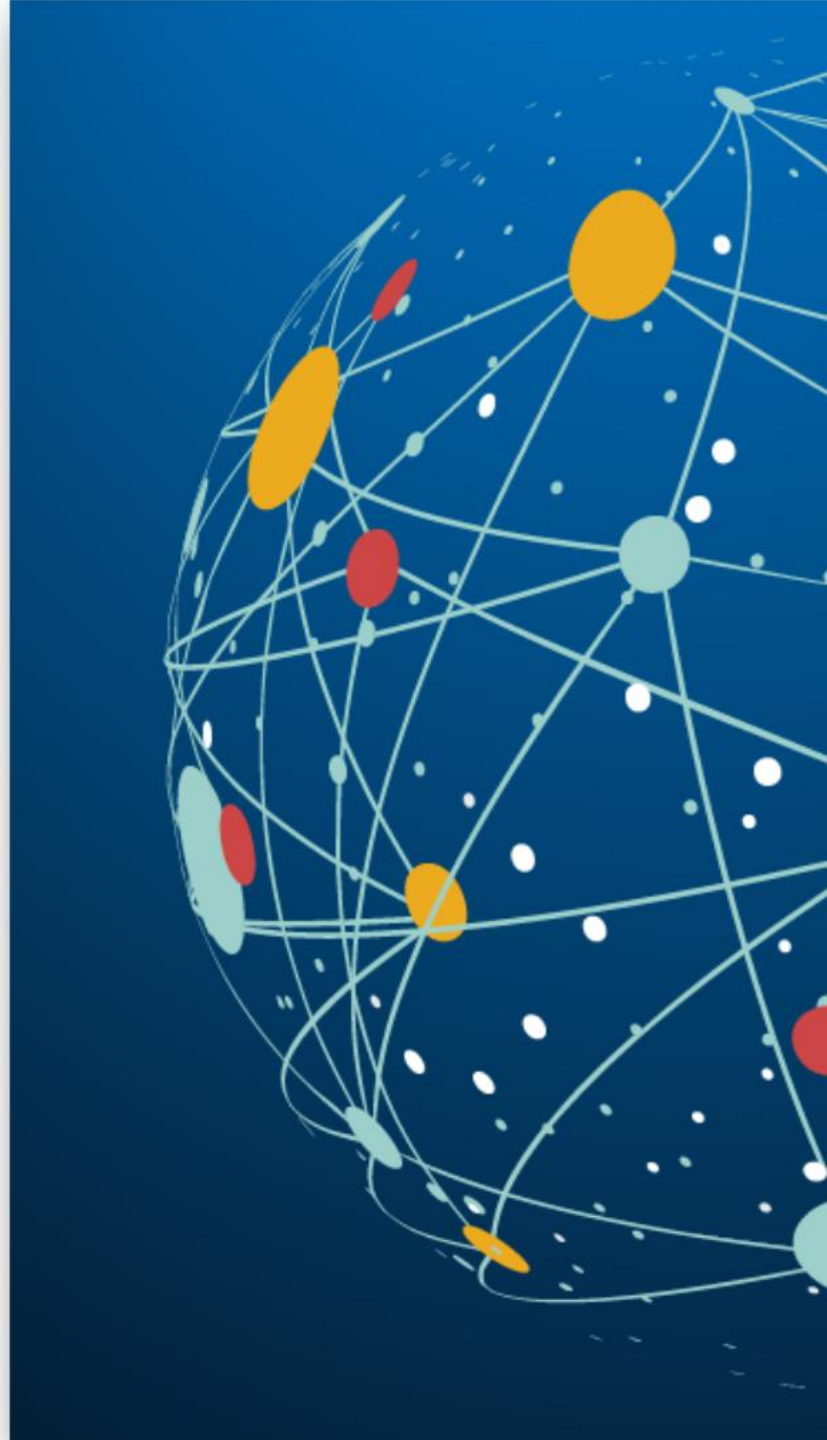
Background & Motivation for Extension

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

CORE as a solution

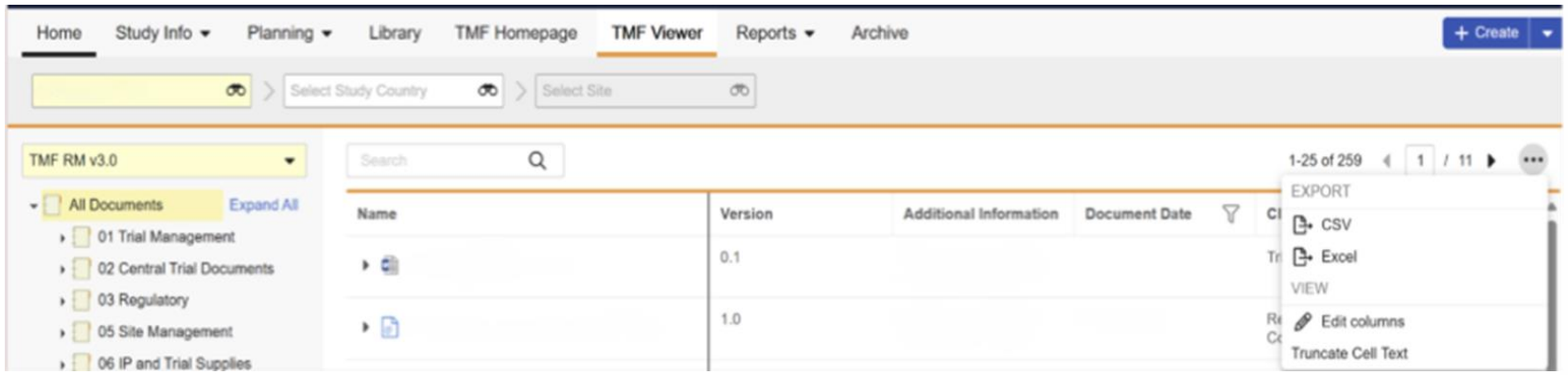
- Addresses the eTMF-specific challenges
- Can perform consistent, comprehensive, and repeatable quality checks across the entire eTMF structure
- Maps TMF Reference Model requirements to rule logic
- Delivers strategic quality oversight
- Is a customizable solution for maintaining documentation quality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



Exploring Validation eTMF
How to….

Exploring Validation eTMF – How to…

eTMF Metadata Extraction



Exploring Validation eTMF - How to…

Structured excel workbook – Metadata

STUDYID	DOCNAME	DOCID	DOCDAT	DOCTYP	DOCSTAT
Study Identifier	Submitted Name	Document Id	Document Date	Document Type	Document Status
Char	Char	Num	Char	Char	Char
9	200	8	8	100	20
STUDY-001	91233726-study-01.01.01-20210929-siraf-tmfr20211021.pdf	5281258	20210929	New Study Info and Risk Assessn	Final
STUDY-001	91233726-study-02.01.01-20211019-IB-v1.0-tmfr20211021.pdf	5367832	20211019	IB	Final
STUDY-001	91233726-study-01.01.01-20211019-CRO_TI Configuration Manual_v1.0-tmfr20211019.xlsx	5368014	20211019	TMF Configuration Manual	Final
STUDY-001	91233726-study-01.05.02-20210930-CTMS Study Set-up (CTSU)-tmfr20211111.pdf	5412986	20210930	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211004-Phase1_Build_Qualification-tmfr20211111pdf	5412987	20211004	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211020-Phase2_Build_Qualification-tmfr20211111pdf	5412988	20211020	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211104-Phase3_Build_Qualification-tmfr20211111pdf	5412989	20211104	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211109-CTMSChangeRequest-tmfr20211111.pdf	5412990	20211109	Tracking Information	Final
STUDY-001	91233726-Study-01.05.03-20210927-SPONSOR Study Internal Meeting Minutes-tmfr20211122.pdf	5445950	20210927	Trial Mgmt Meeting Material	Final
STUDY-001	91233726-Study-01.05.03-20210927-SPONSOR Study Internal Meeting Agenda-tmfr20211122.pdf	5445952	20210927	Trial Mgmt Meeting Material	Final
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STUDY-001	91233726-Study-01.05.03-20211019-SPONSOR Study External Meeting Minutes-tmfr20211123.pdf	5454526	202110		

Library Datasets metadata.xpt etmftree.xpt +

Structured excel workbook – eTMF Reference Model

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

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Exploring Validation eTMF - How to…

How can we make it work ?

TMF Reference Model							Version 3.3.1	11-AUG-2023	
Zone	Zone Name	Section #	Section Name	Artifact	Artifact name	Definition / Purpose	Recommended Subartifacts - Documents/documentation recommended to be filed to the artifact.	Core or Recommended for inclusion	ICH Code
01	Trial Management	01.01	Trial Oversight	01.01.01	Trial Master File Plan	To describe how records for the trial will be managed and stored during and after the trial, including study-specific processes and documentation for archiving and destruction. To include TMF filing structure to be used. May include TMF content list, filing structure and chain of custody records. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	Document Transfer Documentation Evidence of Quality Review Request to Lock TMF Trial Master File Plan Trial Master File Index Trial Master File Report	Recommended	5.5.7
01	Trial Management	01.01	Trial Oversight	01.01.02	Trial Management Plan	To describe overall strategy for timelines, management and conduct of the trial and typically makes reference to other artifacts. Artifact can include details on contingency plan covering details for site start up planning.	Clinical Development Plan Project Management Plan Trial Management Plan	Recommended	2.2
01	Trial	01.01	Trial Oversight	01.01.03	Quality Plan	To describe the operational techniques and activities undertaken	Quality Documentation	Recommended	5.1

Identifiers					Statement of Rule					
Rule ID	Rule ID Version (represents any change to the rule)	Related Rule(s) [See Also, Compare Against	Rule Set	Scope Sectio	Natural Language Rule (Success Criteria)	Rule (Success Criteria)	Natural Language Rule (Failure Criteria)	Rule (Failure Criteria)	Executabilit	Rule Sectio
ETMF0003	1		V3.3.1		The version of the document should be completed	The version of the document is completed	The version of the document is not completed	The version of the document is empty	Fully executable	

ETMF0003 The version of the document should be completed

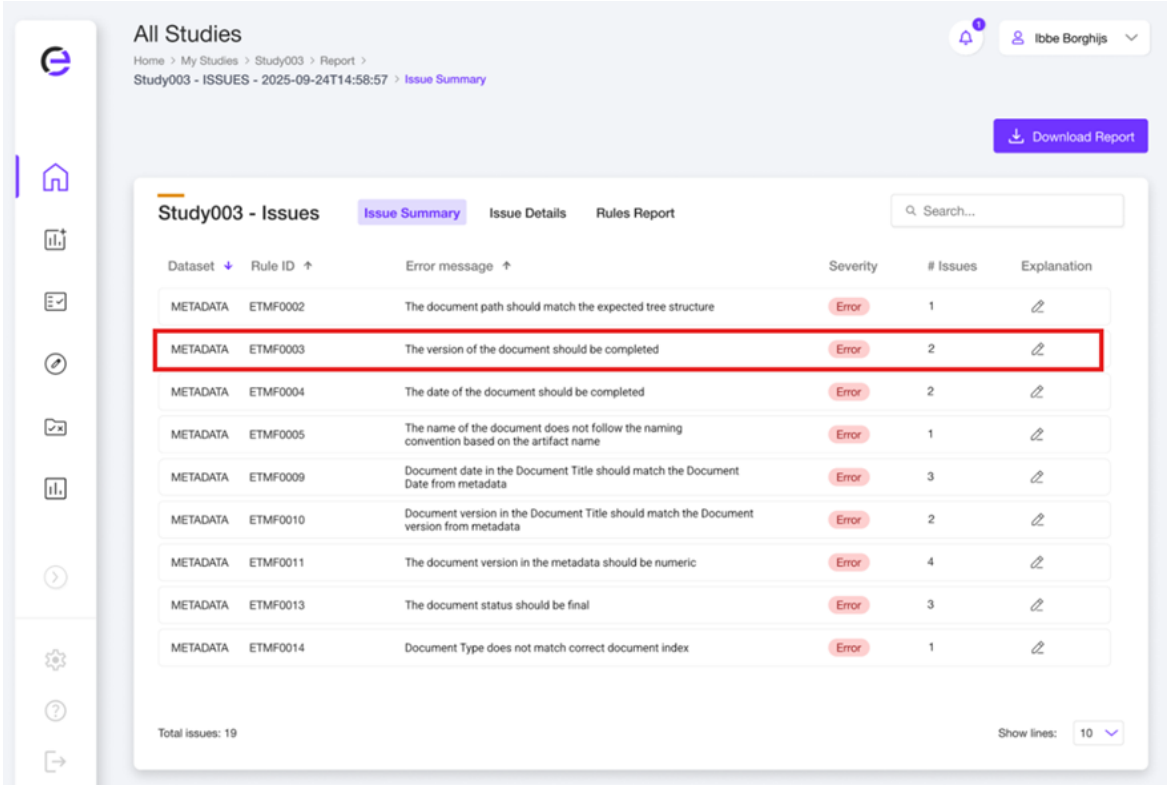
Exploring Validation eTMF - How to…

Defined rules are written in YAML Code

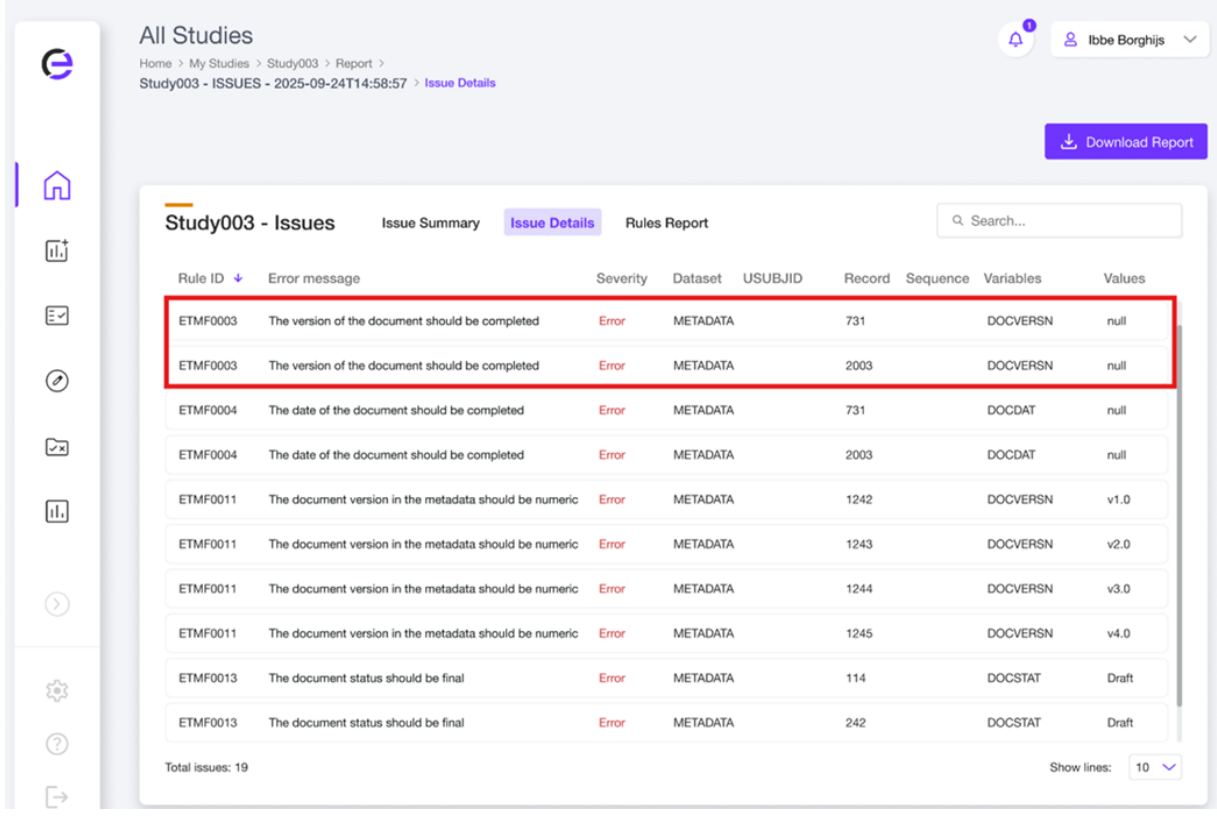
```yaml
            Version: ''
          Version: '3.3.1'
Check:
  all:
    - name: DOCVERSN
      operator: empty
Core:
  Id: ENOVA-000010
  Status: Published
  Version: '1'
Description: 'The version of the document should be completed'
Executability: Fully Executable
Outcome:
  Message: 'The version of the document should be completed'
  Output Variables:
    - DOCVERSN
Rule Type: Record Data
Scope:
  Classes:
    Include:
      - ALL
  Domains:
    Include:
      - ALL
Sensitivity: Record
```

Exploring Validation eTMF - How to…

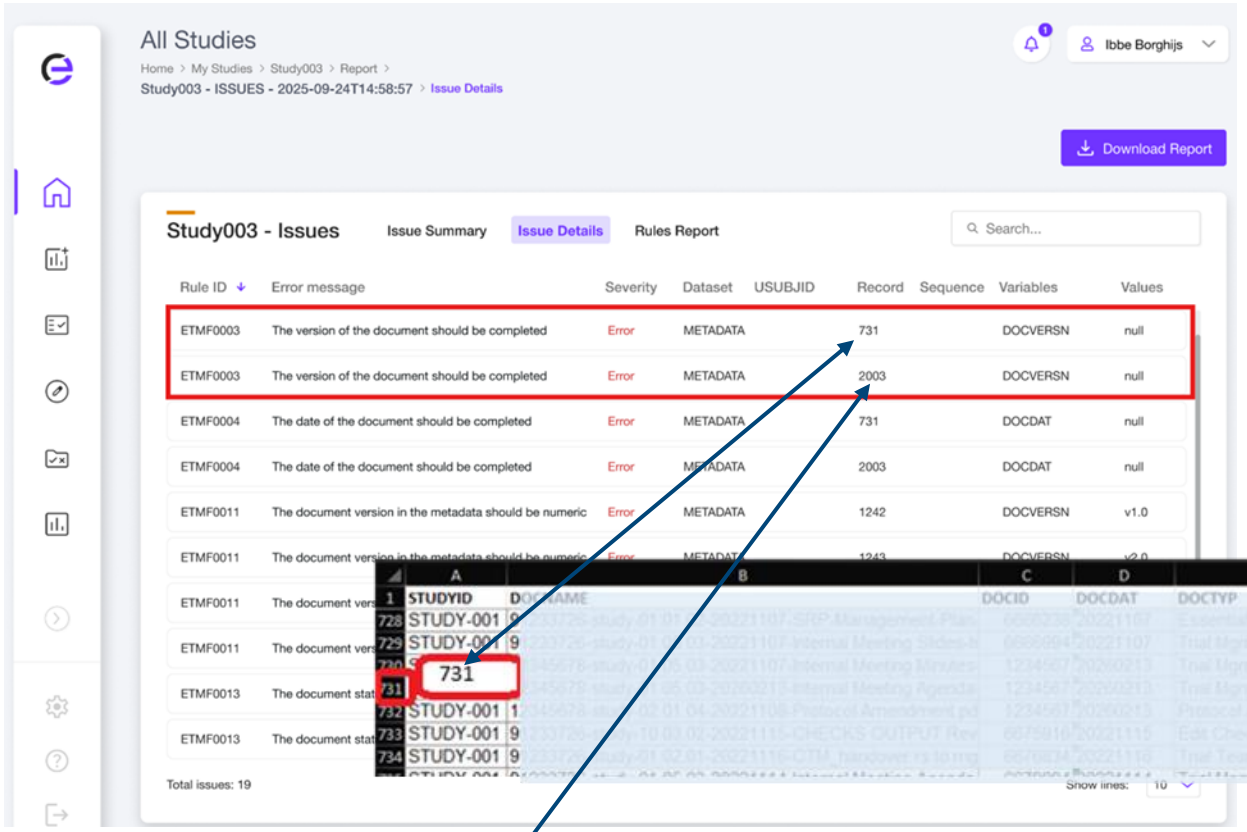
Issue Summary

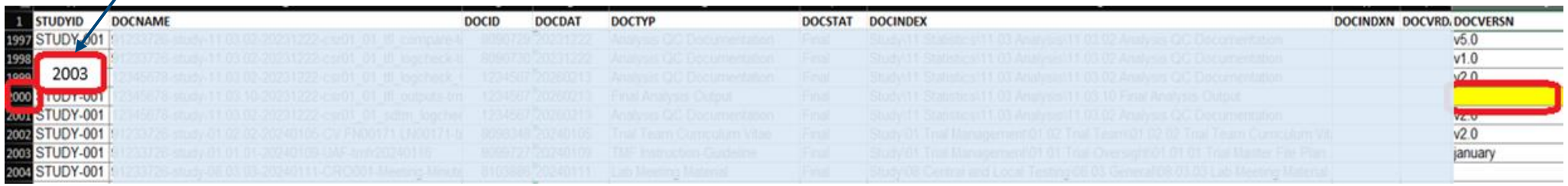


Issue Details

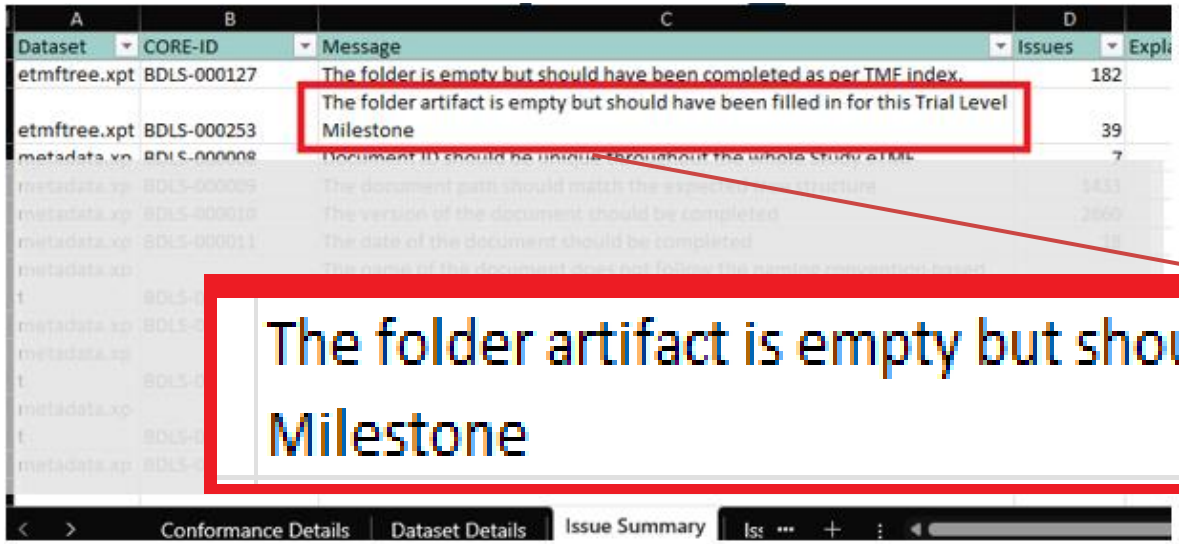


Exploring Validation eTMF - How to…

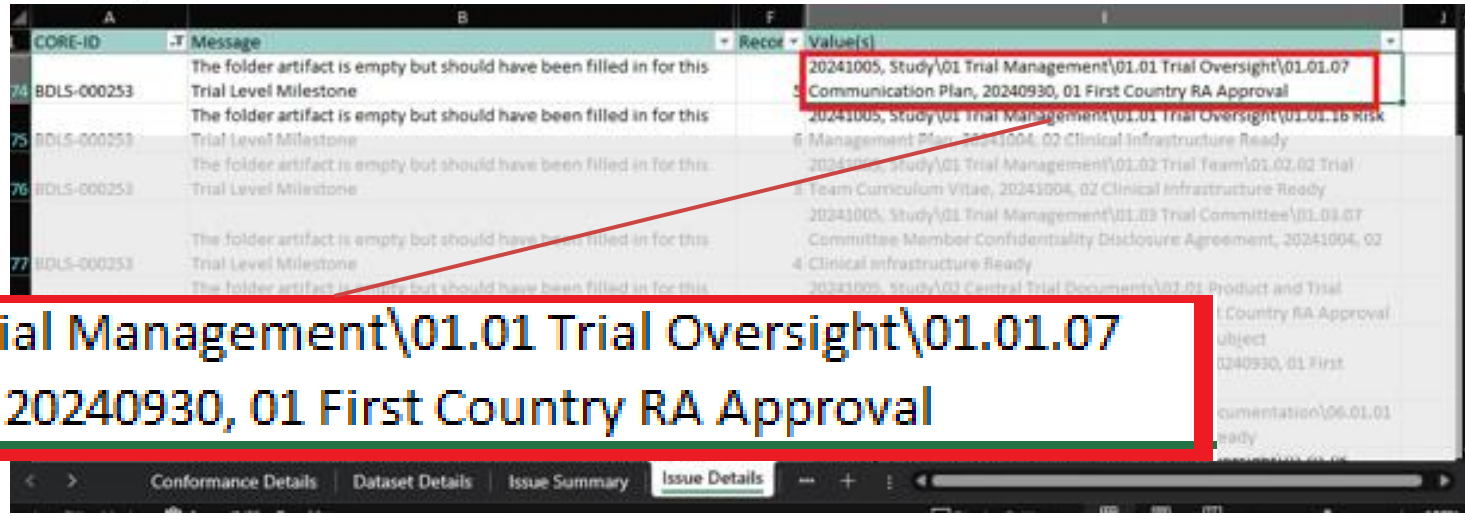




Exploring Validation eTMF - How to…



The folder artifact is empty but should have been filled in for this Trial Level Milestone

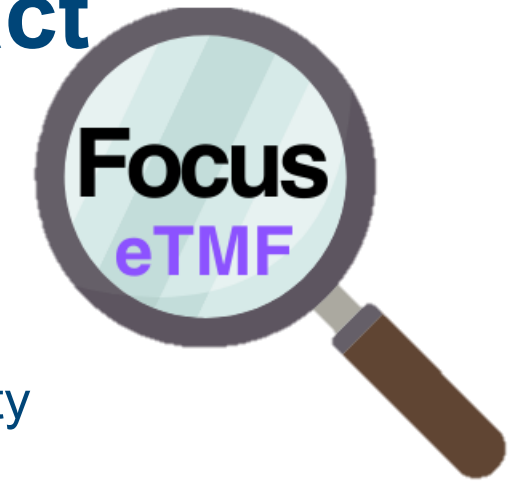


20241005, Study\01 Trial Management\01.01 Trial Oversight\01.01.07 Communication Plan, 20240930, 01 First Country RA Approval

Conclusion - Key Benefits & Strategic Impact

Conclusion - Key Benefits & Strategic Impact

Return on experience – the benefits we found in using the tool



Timeliness

Efficiency

Standardization

Error Reduction

Cost Reduction

Customization

- Delivers strategic quality oversight
- Shift from reactive corrections to proactive quality management
- Continuous, integrated process
- Enhances operational efficiency and regulatory excellence

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Thank You!

Questions?

“CORE can help find your eTMF issues before auditors do.”