



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

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.

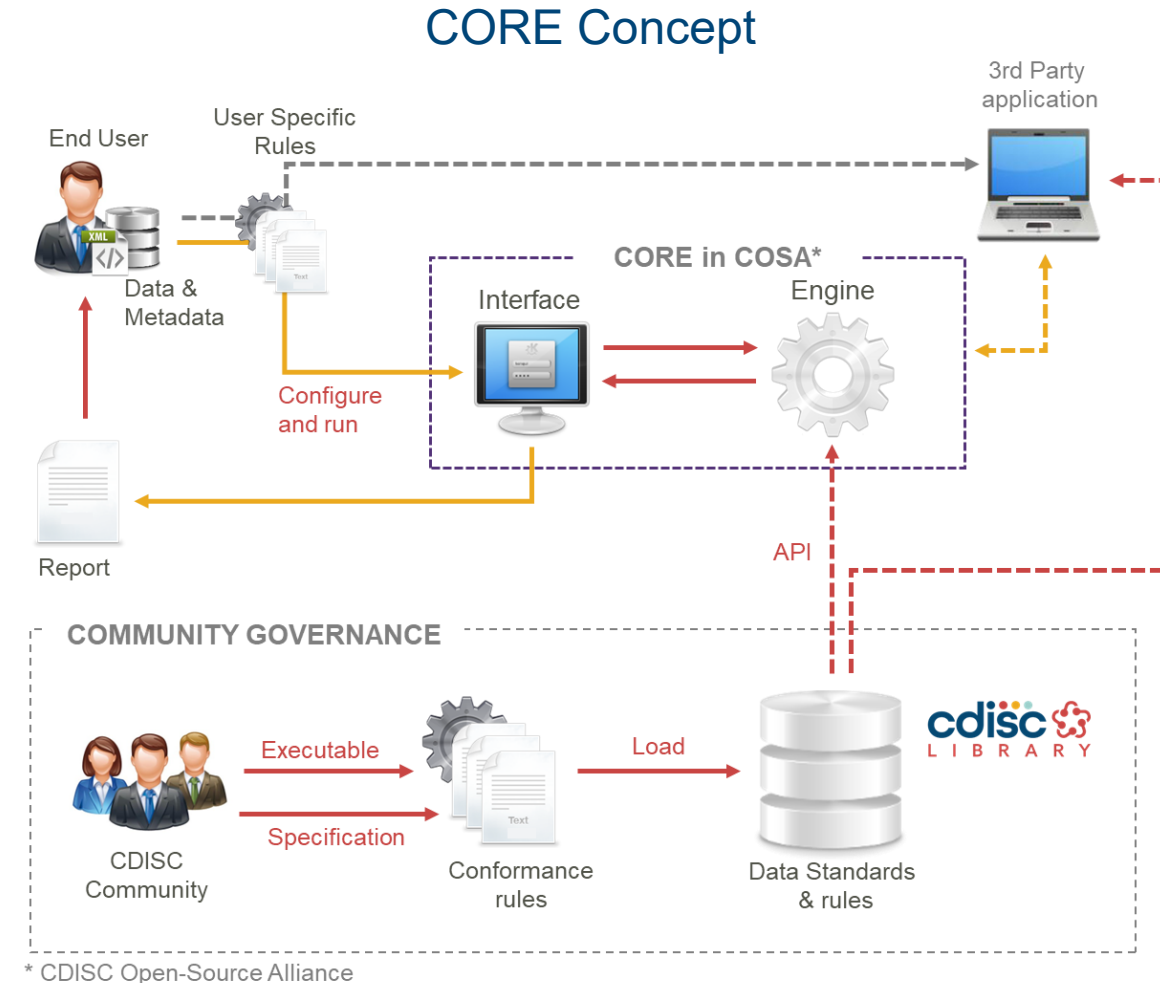
Agenda

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



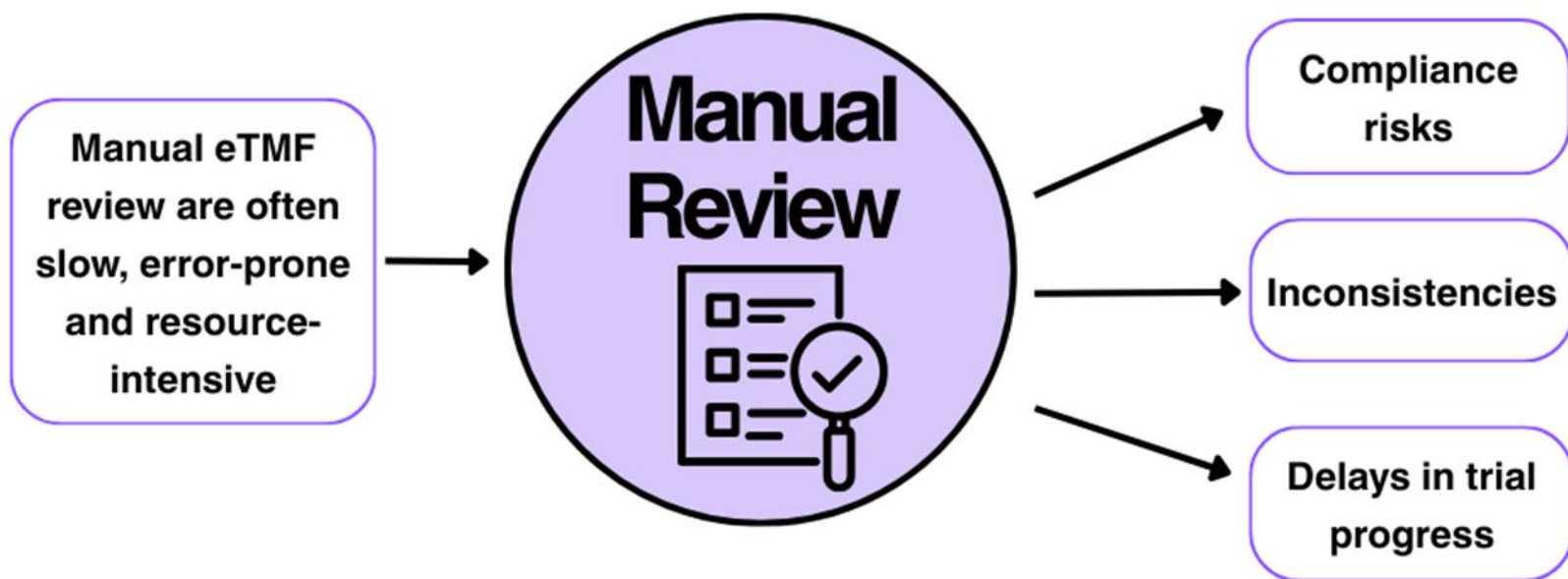
Background & Motivation for Extension

- 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





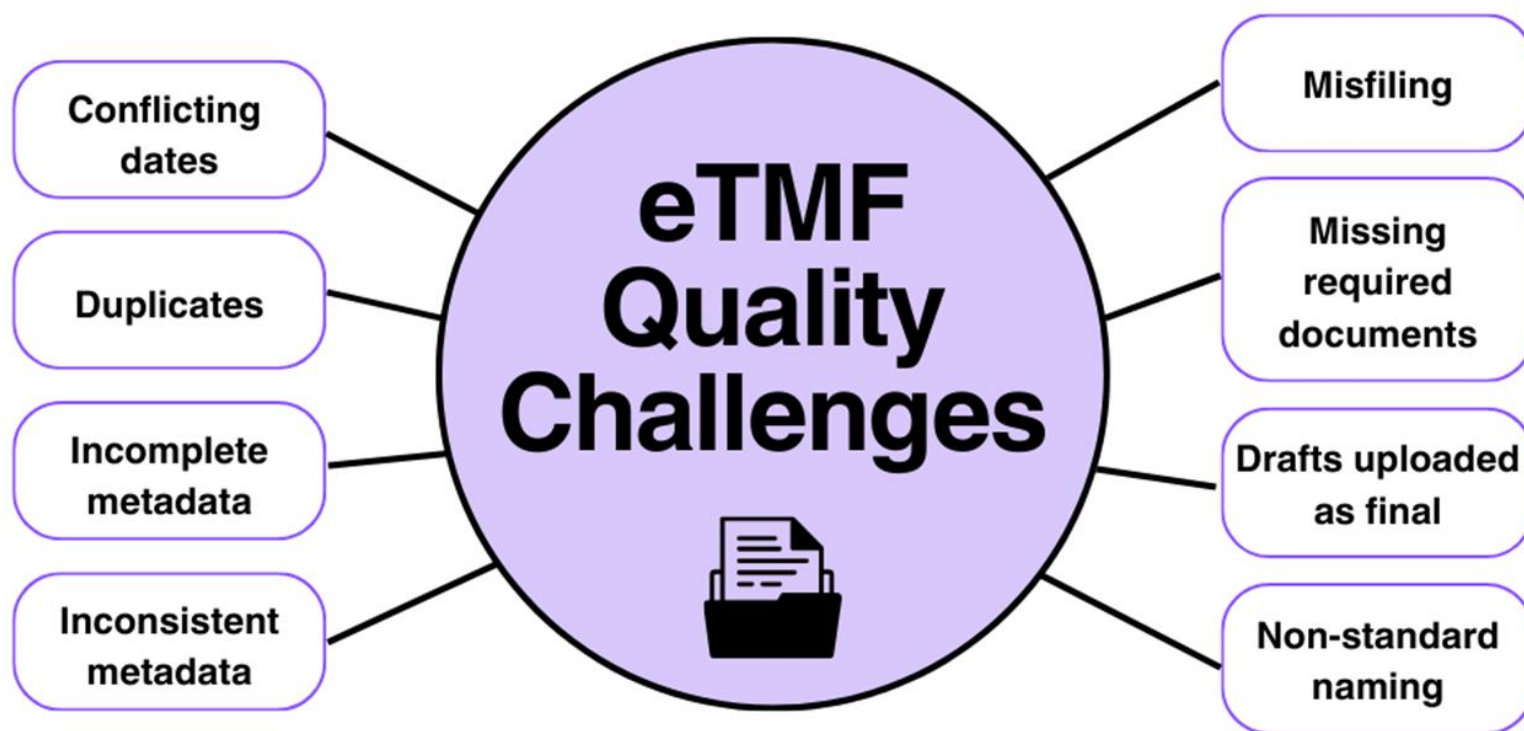
Background & Motivation for Extension



➡ 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

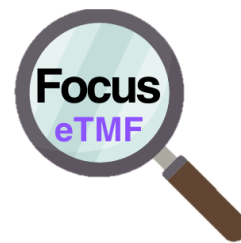




CORE as a Solution



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

A screenshot of the CDISC TMF Viewer web application. The interface includes a top navigation bar with tabs: Home, Study Info, Planning, Library, TMF Homepage, TMF Viewer (active), Reports, and Archive. Below the navigation bar is a search area with a yellow input field and buttons for "Select Study Country" and "Select Site". On the left, a sidebar shows a tree view of document categories under "TMF RM v3.0", including "All Documents", "01 Trial Management", "02 Central Trial Documents", "03 Regulatory", "05 Site Management", and "06 IP and Trial Supplies". The main area displays a table of document metadata with columns: Name, Version, Additional Information, and Document Date. The table shows two rows: one with version 0.1 and another with version 1.0. A context menu is open over the table, showing options: EXPORT (with sub-options CSV and Excel), VIEW, Edit columns, and Truncate Cell Text. The table also has a pagination control showing "1-25 of 259" and "1 / 11".



Exploring Validation eTMF - How to...

Structured excel workbook – Metadata



Structured excel workbook –
eTMF Reference Model

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-tmfr20211111.pdf	5412987	20211004	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211020-Phase2_Build_Qualification-tmfr20211111.pdf	5412988	20211020	Tracking Information	Final
STUDY-001	91233726-study-01.05.02-20211104-Phase3_Build_Qualification-tmfr20211111.pdf	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
STUDY-001	91233726-Study-01.05.03-20211005-SPONSOR Study External Meeting Minutes-tmfr20211123.pdf	5454517	20211005		
STUDY-001	91233726-Study-01.05.03-20211012-SPONSOR Study External Meeting Agenda-tmfr20211123.pdf	5412920	20211012		
STUDY-001	91233726-Study-01.05.03-20211012-SPONSOR Study External Meeting Minutes-tmfr20211123.pdf	5454521	20211012		
STUDY-001	91233726-Study-01.05.03-20211012-SPONSOR Study External Meeting Presentation-tmfr20211123.pdf	5454523	20211012		
STUDY-001	91233726-Study-01.05.03-20211019-SPONSOR Study External Meeting Agenda-tmfr20211123.pdf	5454525	20211019		
STUDY-001	91233726-Study-01.05.03-20211019-SPONSOR Study External Meeting Minutes-tmfr20211123.pdf	5454526	20211019		

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

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	Natural Language Rule (Success Criteria)	Rule (Success Criteria)	Natural Language Rule (Failure Criteria)	Rule (Failure Criteria)	Executability	Rule Section
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	



Exploring Validation eTMF - How to...

Defined rules are written in YAML Code

```
23 |         Version: ''
24 |         Version: '3.3.1'
25 | Check:
26 |   all:
27 |     - name: DOCVERSN
28 |       operator: empty
29 | Core:
30 |   Id: ENOVA-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
```



Exploring Validation eTMF - How to...



Issue Summary

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

Issue Details

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

Download Report

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		DOCSTAT	null
ETMF0004	The date of the document should be completed	Error	METADATA		2003		DOCSTAT	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

	A	B	C	D	E	F	G	H	I	J
	STUDYID	DOCNAME	DOCID	DOCDAT	DOCTYP	DOCSTAT	DOCINDEX	DOCINDXN	DOCVRD	DOCVRSN
728	STUDY-001	20221107-SRP Management Plan	0000236	20221107	Essential Documents Review Plan	Final	Study 01 Trial Management 01 01 Trial Oversight 01 01 02 Trial Management Plan			v2.0
729	STUDY-001	20221107 Internal Meeting Slides	0000994	20221107	Trial Mgmt Meeting Material	Final	Study 01 Trial Management 01 05 General 01 05 03 Trial Mgmt Meeting Material			V1.0
730	STUDY-001	20221107 Internal Meeting Minutes	1234567	20220913	Trial Mgmt Meeting Material	Final	Study 01 Trial Management 01 05 General 01 05 03 Trial Mgmt Meeting Material			V1.0
731	731	20221107 Internal Meeting Agenda	1234567	20220913	Trial Mgmt Meeting Material	Final	Study 01 Trial Management 01 05 General 01 05 03 Trial Mgmt Meeting Material			V1.0
732	STUDY-001	20221108 Protocol Amendment v01	1234567	20220913	Protocol Amendment	Final	Study 02 Central Trial Documents 02 01 04 Protocol Amendment			v2.0
733	STUDY-001	20221115 CHECKS OUTPUT REV	0075810	20221115	Edi Check Plan	Final	Study 10 Data Management 10 03 Database 10 03 02 Edi Check Plan			v3.0
734	STUDY-001	20221116 CTM handover to IRG	0076834	20221116	Trial Team Details	Final	Study 01 Trial Management 01 07 Trial Team 01 02 01 Trial Team Details			v2.0

1	STUDYID	DOCNAME	DOCID	DOCDAT	DOCTYP	DOCSTAT	DOCINDEX	DOCINDXN	DOCVRD	DOCVERSN
1997	STUDY-001	1234567-study-11-03-02-2023-1222-cs01_01_ill-compare-1	8098729	20231222	Analysis QC Documentation	Final	Study-11-Statistics-11-03-Analysis-11-03-02-Analysis QC Documentation			v5.0
1998	STUDY-001	1234567-study-11-03-02-2023-1222-cs01_01_ill-log-check-1	8098730	20231222	Analysis QC Documentation	Final	Study-11-Statistics-11-03-Analysis-11-03-02-Analysis QC Documentation			v1.0
1999	STUDY-001	12345678-study-11-03-02-2023-1222-cs01_01_ill-log-check-1	1234567	20260213	Analysis QC Documentation	Final	Study-11-Statistics-11-03-Analysis-11-03-02-Analysis QC Documentation			v2.0
2000	STUDY-001	12345678-study-11-03-10-2023-1222-cs01_01_ill-output-1m	1234567	20260213	Final Analysis Output	Final	Study-11-Statistics-11-03-Analysis-11-03-10-Final Analysis Output			
2001	STUDY-001	12345678-study-11-03-03-2023-1222-cs01_01_adm-log-check	1234567	20260213	Analysis QC Documentation	Final	Study-11-Statistics-11-03-Analysis-11-03-02-Analysis QC Documentation			v2.0
2002	STUDY-001	12345678-study-01-02-02-2024-0105-CV-FHX00171-1X00171-1	8098748	20240105	Trl Team Curriculum Vitae	Final	Study-01-Trial Management-01-02-Trial Team-01-02-02-Trial Team Curriculum Vitae			v2.0
2003	STUDY-001	12345678-study-01-01-01-2024-0105-IMF-FHX00171-1X00171-1	8098729	20240109	TMF Instructional Guideline	Final	Study-01-Trial Management-01-01-Trial Oversight-01-01-01-Trial Master File Plan			january
2004	STUDY-001	12345678-study-01-01-01-2024-0111-CR0001-Meeting Minutes	8098748	20240111	Lab Meeting Material	Final	Study-09-Central and Local Testing-01-01-01-01-01-Lab Meeting Material			

Exploring Validation eTMF - How to...



A	B	C	D	E
Dataset	CORE-ID	Message	Issues	Expl
etmftree.xpt	BDLS-000127	The folder is empty but should have been completed as per TMF index.	182	
etmftree.xpt	BDLS-000253	The folder artifact is empty but should have been filled in for this Trial Level Milestone	39	
metadata.xpt	BDLS-000008	Document ID should be unique throughout the whole Study eTMF	7	
metadata.xpt	BDLS-000009	The document path should match the expected structure	1433	
metadata.xpt	BDLS-000010	The version of the document should be completed	2860	
metadata.xpt	BDLS-000011	The date of the document should be completed	18	
metadata.xpt	BDLS-000012	The name of the document should not follow the naming convention		
t	BDLS-000013			
metadata.xpt	BDLS-000014			
metadata.xpt	BDLS-000015			
t	BDLS-000016			
metadata.xpt	BDLS-000017			
t	BDLS-000018			
metadata.xpt	BDLS-000019			

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

A	B	F	I
CORE-ID	Message	Record	Value(s)
74 BDLS-000253	The folder artifact is empty but should have been filled in for this Trial Level Milestone	5	20241005, Study\01 Trial Management\01.01 Trial Oversight\01.01.07 Communication Plan, 20240930, 01 First Country RA Approval
75 BDLS-000253	The folder artifact is empty but should have been filled in for this Trial Level Milestone	6	20241005, Study\01 Trial Management\01.01 Trial Oversight\01.01.16 Risk Management Plan, 20241004, 02 Clinical Infrastructure Ready
76 BDLS-000253	The folder artifact is empty but should have been filled in for this Trial Level Milestone	7	20241005, Study\01 Trial Management\01.02 Trial Team\01.02.02 Trial Team Curriculum Vitae, 20241004, 02 Clinical Infrastructure Ready
77 BDLS-000253	The folder artifact is empty but should have been filled in for this Trial Level Milestone	8	20241005, Study\01 Trial Management\01.03 Trial Committee\01.03.07 Committee Member Confidentiality Disclosure Agreement, 20241004, 02 Clinical Infrastructure Ready
	The folder artifact is empty but should have been filled in for this Trial Level Milestone	9	20241005, Study\01 Central Trial Documents\01.01 Product and Trial Information\01.01.01 Country RA Approval Subject, 20240930, 01 First Country RA Approval
	The folder artifact is empty but should have been filled in for this Trial Level Milestone	10	20241005, Study\01 Central Trial Documents\01.01 Product and Trial Information\01.01.02 Country RA Approval Documentation\06.01.01 Country RA Approval Documentation, 20241004, 02 Clinical Infrastructure Ready

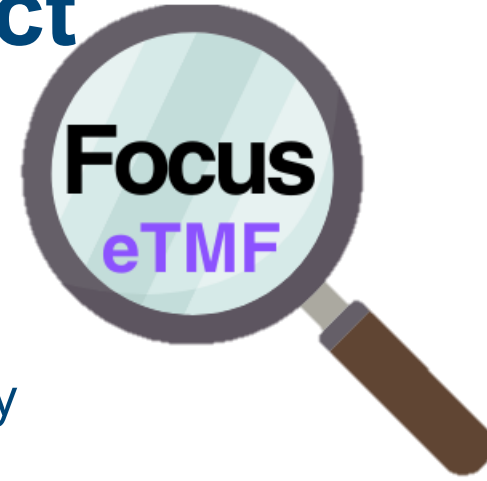
20241005, Study\01 Trial Management\01.01 Trial Oversight\01.01.07 Communication Plan, 20240930, 01 First Country RA Approval



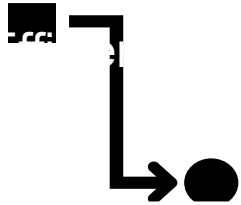
Conclusion - Key Benefits & Strategic Impact

Conclusion - Key Benefits & Strategic Impact

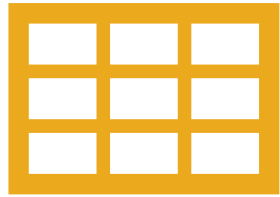
Return on experience – the benefits we found in using the tool



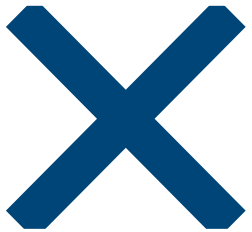
Timeliness



Efficiency



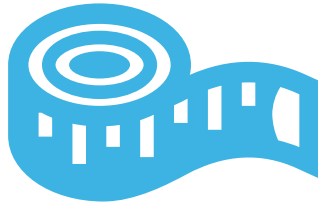
Standardization



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



Thank You!





Questions?





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

