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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



From Daily Operations to Audit Spotlight: Standardizing Document Management and Quality Assurance Collaboration

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Speakers



Cristina is a Document Management Associate at SGS, a role she has held since 2022. She supports clinical studies through eTMF quality control, document management, user administration, and system training, contributing to TMF completeness and inspection readiness.

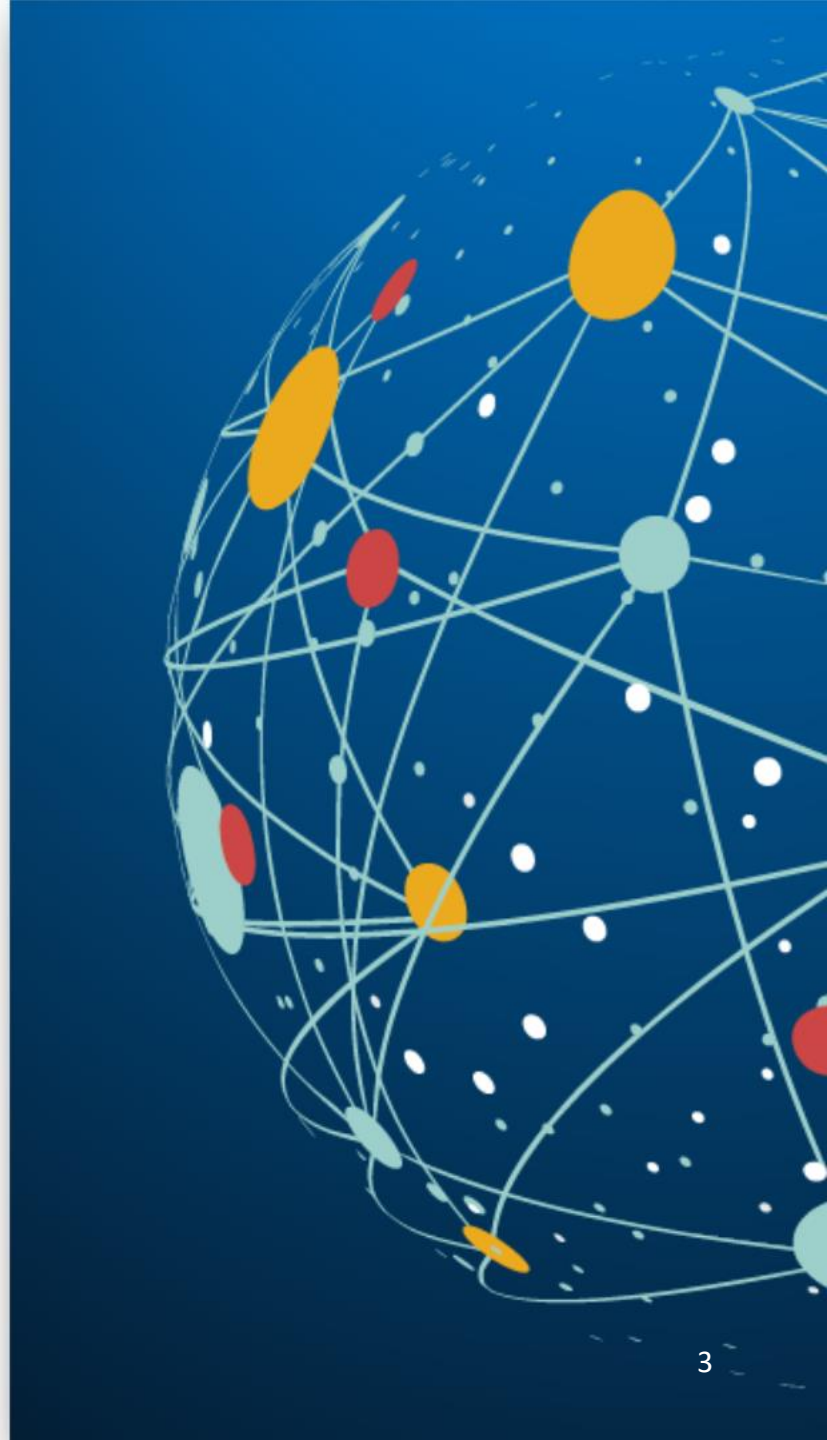
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Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC or SGS Pharma.*
- *The authors have no real or apparent conflicts of interest to report.*



Agenda

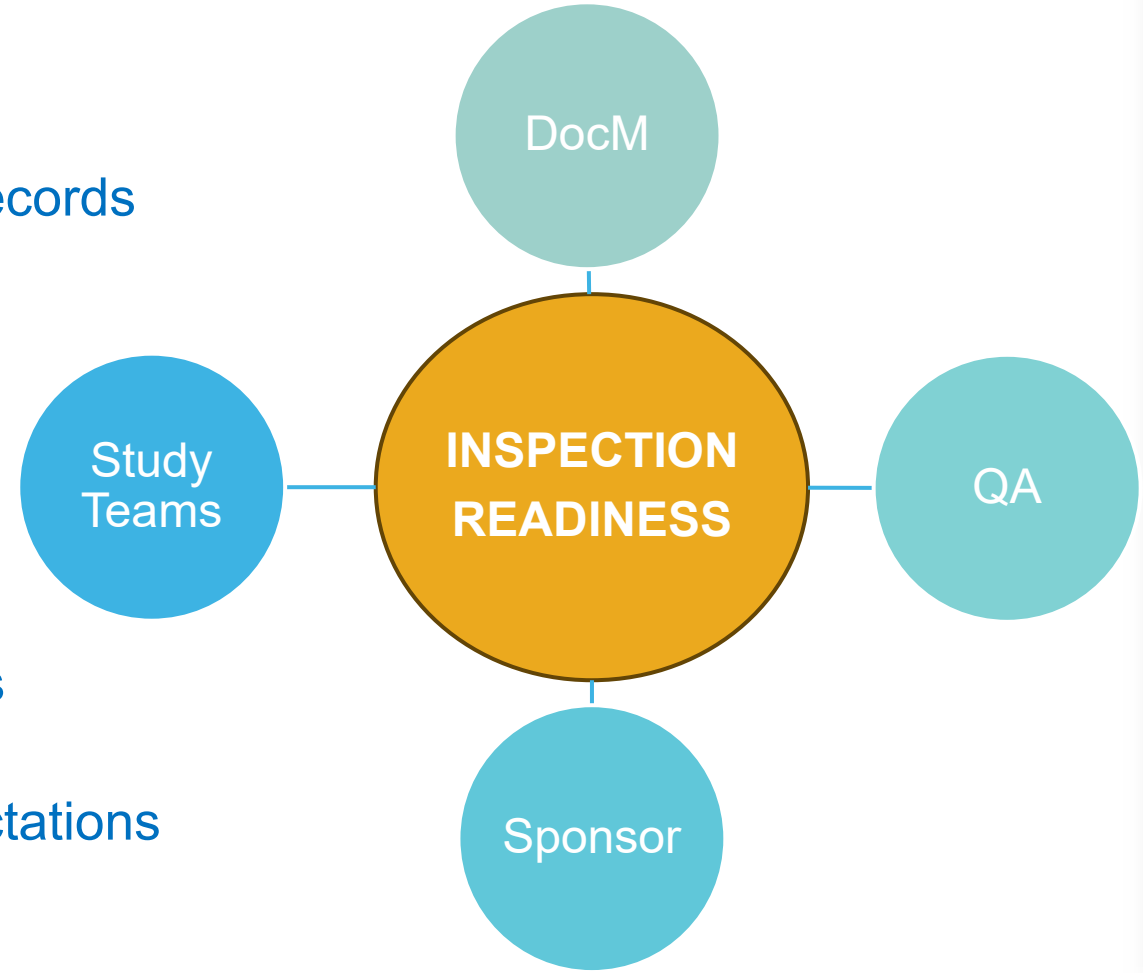
1. Why Collaboration Matters
2. Real Examples of Collaborative Quality Improvements
3. Creating an Audit-Ready eTMF Every Day
4. Future Opportunities for Risk-Based eTMF Management

Why Collaboration Matters

Communication as the Foundation

Why Inspection Readiness Requires Collaboration

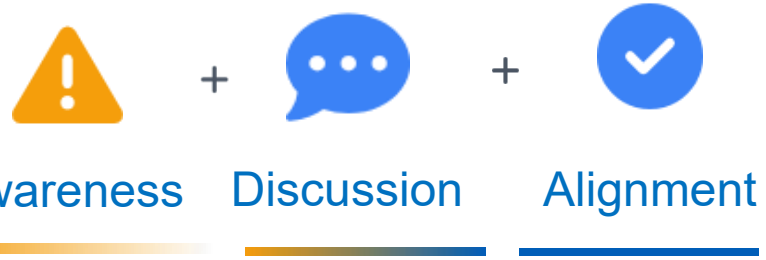
- Extensive TMF records
- Cross-functional contributors
- Multiple systems
- Different priorities
- Regulatory expectations



Inspection readiness emerges when perspectives are connected

Communication as the Foundation

- Regular communication
- Shared interpretation of requirements
- Consistent decision making
- Escalation when needed



EXAMPLE IN ACTION:

- Bi-weekly QA-DocM meetings
- Dedicated Operational Quality Manager
- Review of key QC findings
- Consultation on complex quality issue resolution
- Alignment on potential compliance risks



Many risks are prevented through discussion long before they become findings

From Collaboration to Action

How QA and DocM translate collaboration into inspection readiness

QC Starts With Consistency

QC Review
- DocM review documents

Common Interpretation
- QA Guidance & QC Manual

Consistent Decision
- Same issue → Same Outcome

Scalable Quality System



A common quality language transforms individual reviews into a scalable quality system

From Findings to Improvement

A joint QA-DocM initiative transformed QC observations into targeted training and quality improvements

2023

BASELINE ASSESSMENT

37.8%

QC Comment Rate

Training Awareness

75%

Reduction in QC comments

Process Improvement

2026

3 ONGOING STUDY QCS

9.5%

QC Comment Rate

QA CONTRIBUTION

- ✓ Trend identification
- ✓ Quality oversight
- ✓ Training initiative

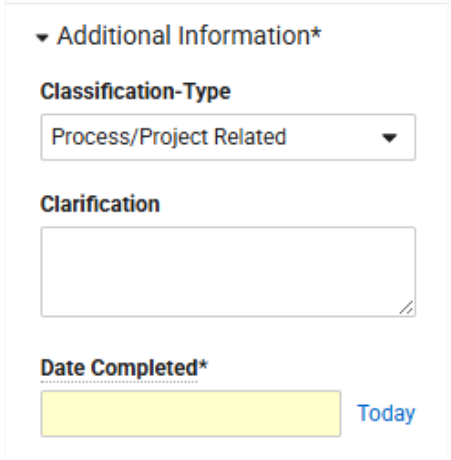
DOCM CONTRIBUTION

- ✓ QC execution
- ✓ Detailed findings analysis
- ✓ Process standardization

From NTFs to Structured Clarification

The Additional Information Field

NTFs



The Challenge

458

NTFs 2020-2021

The Shift

Additional Information field

Implemented in December 2021

- Guided by the Decision Tree
- Linked to document version
- Visible to Sponsor

The Impact

90

NTFs 2025

REAL STUDY EXAMPLE
700+ final documents
20 Additional Information entries
20 Potential NTFs avoided

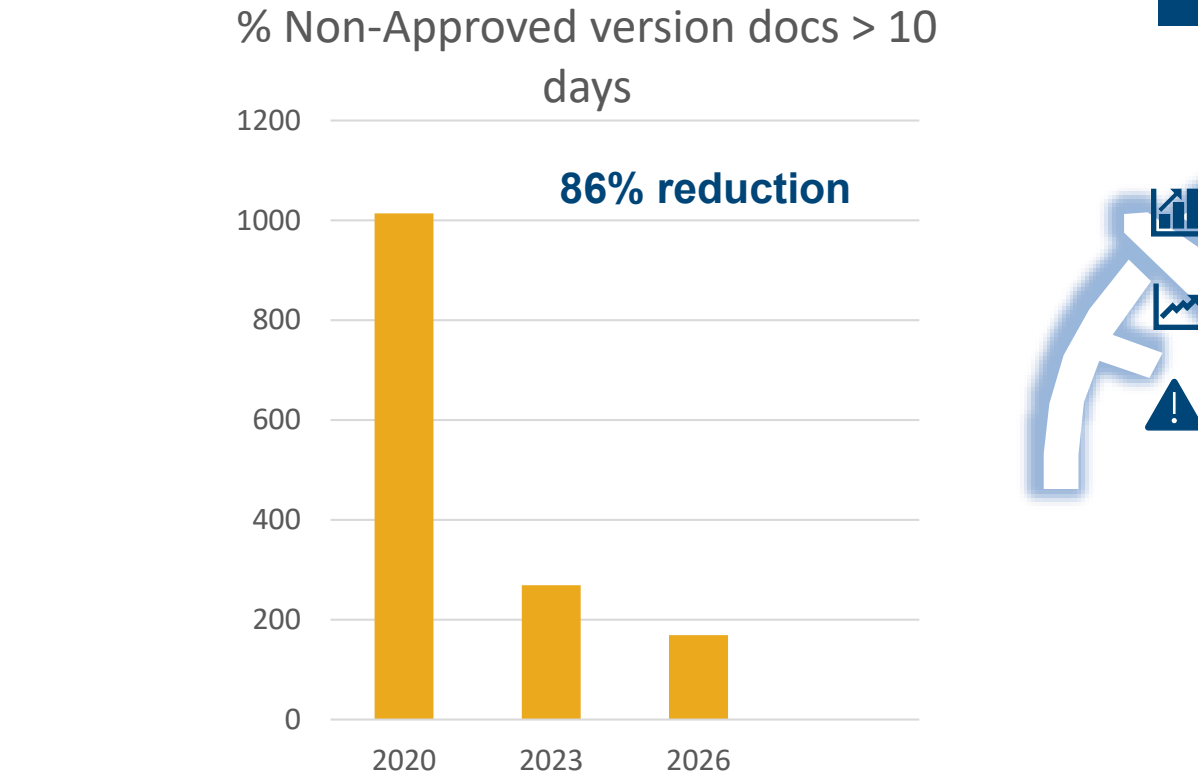
From detailed Monitoring to Risk-Based Oversight

The eTMF Metrics Report

The initial approach

2020

- Quarterly follow-up
- Reports and Feedbacks
- Manual reviews



The current model

2026

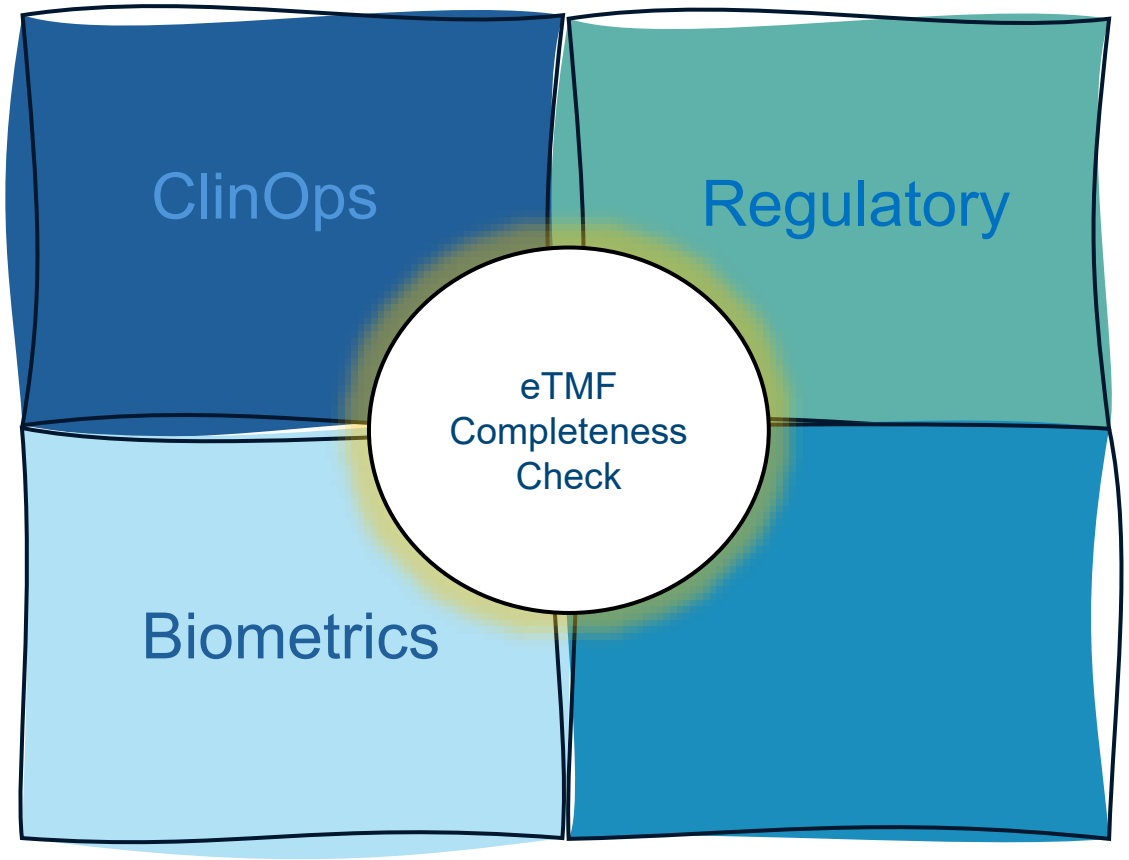
- KPI monitoring
- Trend analysis
- Risk-based escalation

Joint effort → Improvements → Risk oversight

eTMF Check: Shared Ownership of eTMF Completeness

The eTMF Completeness Report

DocM
Implementation and Follow-up



QA
Coordination and Guidance

A complete TMF is only achieved when all functional areas contribute their piece

When Readiness Meets Audit Reality

How collaboration becomes visible during an audit

Audits Don’t Create Readiness



Before the Audit: Creating a Transparent Review Environment

QA

- Coordinates audit preparation
- Readiness assessment and preparation meetings
- Planning

DocM

- Provides mandatory eTMF system orientation
- Prepares auditor access
- Enables controlled transparency



Efficient, controlled and compliant auditor access

During the Audit: One Team, One Process

QA

- Primary audit host and central point of contact
- Oversees auditor communications
- Coordinate auditor interactions

DocM

- eTMF support and assistance
- Team support in eTMF questions
- Ensure traceability

Confidentiality – Traceability – Data Integrity

After the Audit: From Findings to Learning

ACCESS REMOVED

Auditor access is promptly deactivated



QA Follow up

- Observations
- Responses
- CAPA activities



DocM Traceability

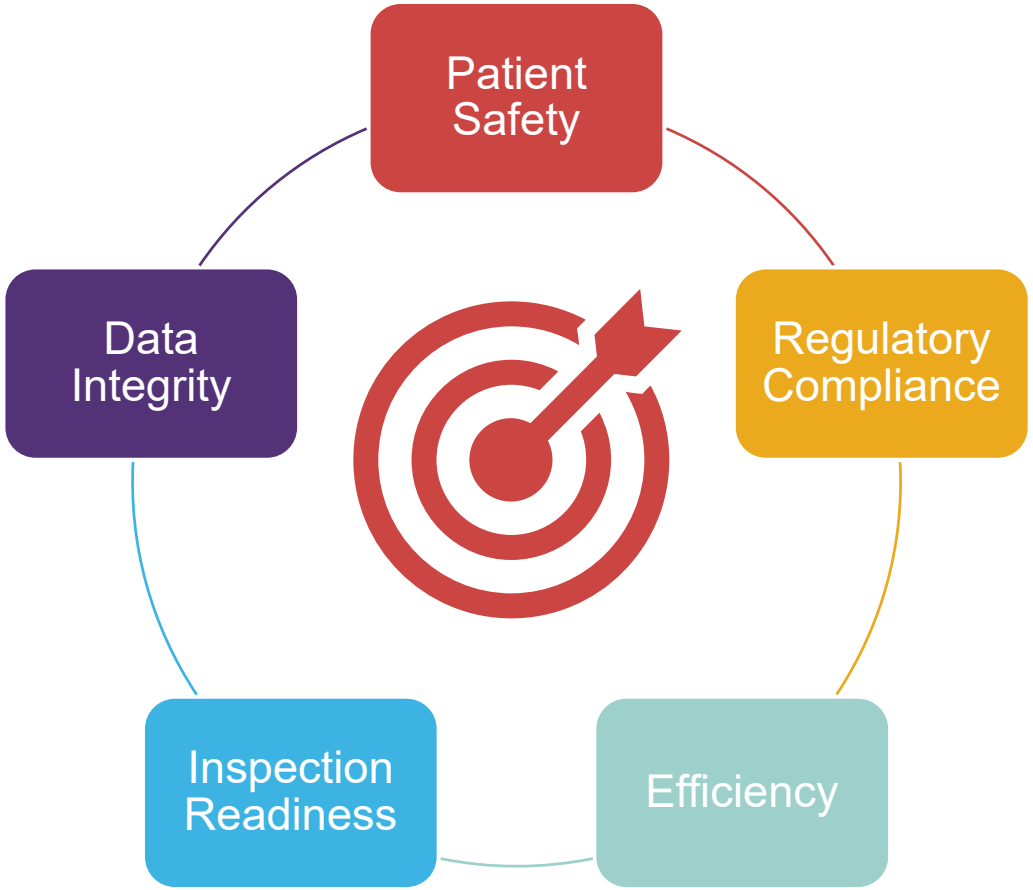
- Supports compliant TMF
- Management and record traceability



Conclusion

The new RBQM Project

Looking Ahead: RBQM Improved Filing Project





As eTMF processes continue to evolve, where should we focus our effort to create the greatest value?

Thank You!

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