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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

From Essential Documents to Essential Records: Building ICH E6(R3) into the Future CDISC TMF Standard Model

Lisa Mulcahy, Mulcahy Consulting, LLC

Speaker

Lisa Mulcahy
Mulcahy Consulting, LLC

- Lisa Mulcahy has an extensive career in the biopharmaceutical industry in the areas of Clinical Operations, Quality Management, and TMF Management. She utilizes her experiences associated with15 years of previous site, CRO, biotech, pharmaceutical based positions with her last 20 years of expertise as an independent consultant to assist her biotech clients to develop, revise, and operationalize high-quality and compliant electronic TMF management systems, processes, and resources to achieve complete and inspection-ready of TMFs.

- Lisa is a member of the management committee who are driving the transformation of the CDISC TMF Reference Model to the CDISC TMF Standard Model. She is a current CDISC TMF Community Steering Committee member and a certified CDISC trainer who creates and delivers CDSIC TMF-related courses.

From Essential Documents to Essential Records: Building ICH E6(R3) into the Future CDISC TMF Standard Model.

Why this Matters Now

- ICH GCP(R3):
  - Introduces a framework for compliance that extends beyond traditional document creation and designation of some the documentation as essential.
  - Requires organizations to demonstrate oversight through a broader set of records.

ICH GCP(R3)

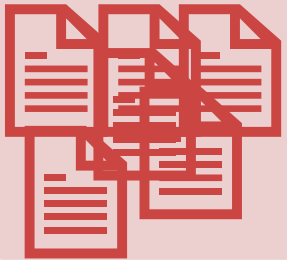
Clinical trials vary widely in scale, complexity and cost. Careful evaluation of critical to quality factors involved in each trial and the risks associated with these factors will help ensure efficiency by focusing on activities critical to achieving the trial objectives.

Section 1: Introduction

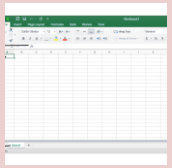
The nature and extent of … records generated and maintained are dependent on the trial design, its conduct, application of risk proportionate approaches and the importance and relevance of that record to the trial.

Annex C: C.1.1

Current TMF Models have Shortcomings



Still reflects largely static, document-centric structures.

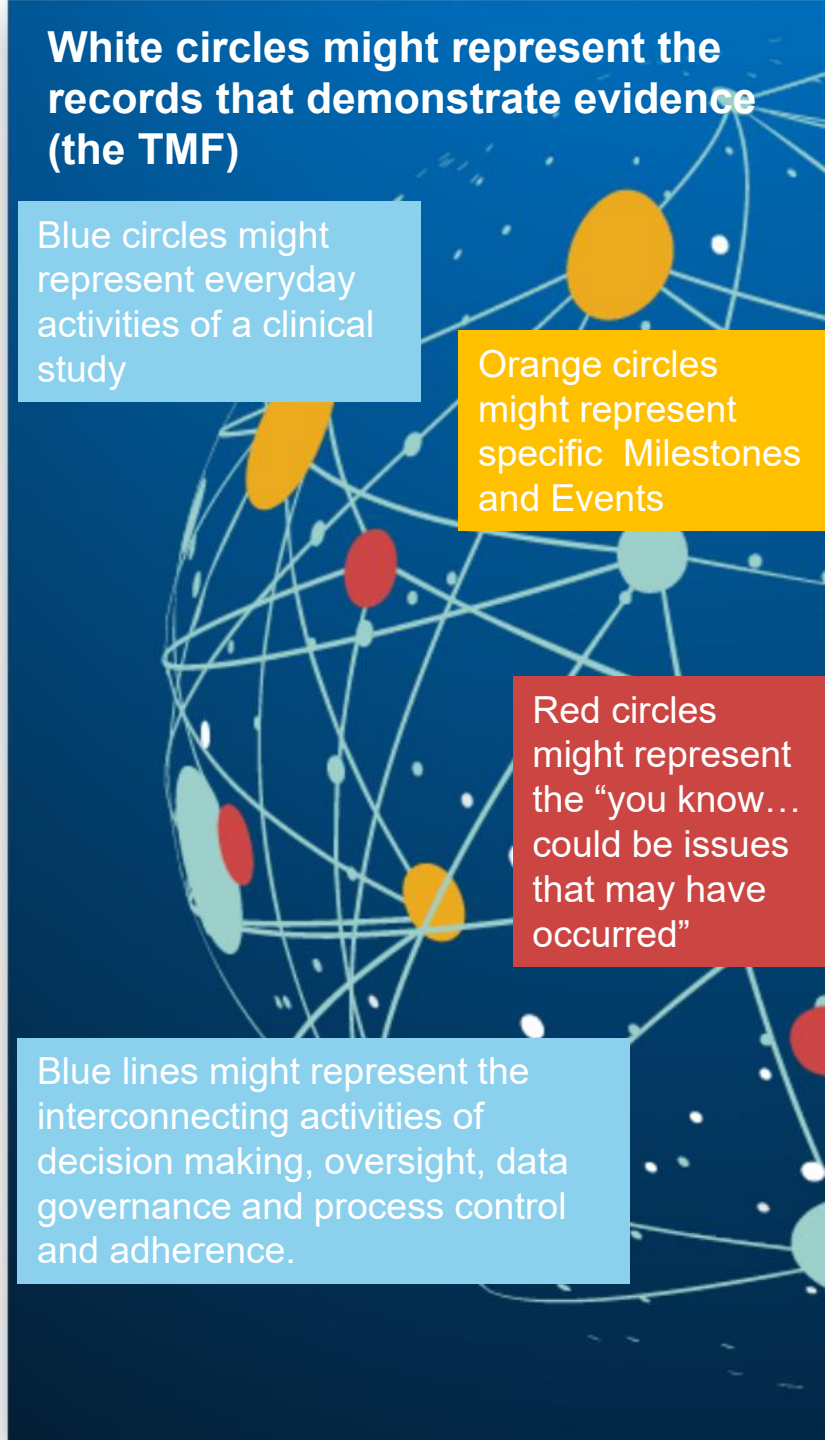


A checklist approach that is missing entire categories of records that show compliance with ICH GCP(R3).

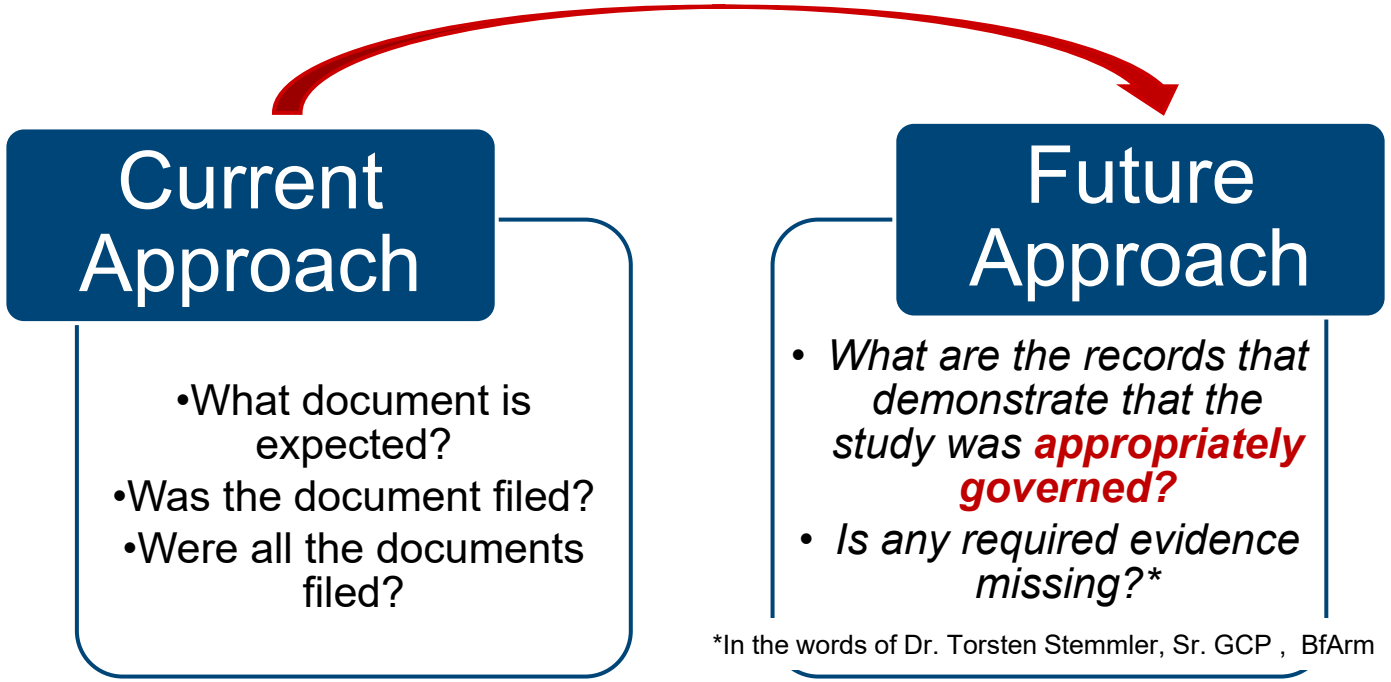
Resulting in organizations missing critical records in their TMFs

The Compliance Shift

- An evolution is occurring from the historically defined expected list of essential documents to now, under ICH GCP E3, to a TMF that focuses on records created during the clinical study, demonstrating evidence of:
  - Decision-making
  - Oversight
  - Data governance
  - Service provider management
  - Process control/adherence and oversight



The Future TMF Model Must Account for this Shift



"Appropriately governed" means the entity (clinical study) is being run in a way that is lawful, fair, transparent, and accountable, meeting both legal requirements and best governance practices.

- The future TMF cannot be built around a universal checklist of essential documents.
  - An essential documents is an obsolete term and concept
- The TMF Standard Model is reshaping the framework of the records created/collected that are needed to demonstrate clinical trial compliance with laws/regulations and ICH GCP R3.

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The CDISC TMF SM – Bringing ICH GCP (R3) into the TMF RM

- The CDISC TMF RM will use ICH GCP(R3) as the foundation for defining record types and record groups.
  - This includes ICH GCP(R3) expectations for the evidence that organizations need to retain, govern, and produce during health authority inspections.

The CDISC TMF Standard Model

- Structured in alignment with ICH E6 (R3)
- Enable cross-zone grouping of related records
- Record groupings may be those associated with:
  - Trial Management
  - Agreements
  - Qualifications and Training
  - Risk-based quality management
  - Sponsor oversight
  - Investigator oversight
  - Service Provider oversight
  - Data governance and data flow
  - eClinical System
  - Decentralized trial activity
  - Data review and data reliability

ICH GCP(R3) give us a foundation and the CDISC TMF Standard Model will give the operational structure to make that foundation usable.

Operationalizing ICH GCP(R3) in terms of a Trial Master File

- The CDISC TMF Standard Model will contain many new Record Types*
  - An esteemed group of industry volunteers, your colleagues, reviewed the entire ICH GCP(R3) document and identified new and revised records that were not currently in the TMF RM v3.3.1*.
  - The records will be included as Record Types.
  - Record Groups based on ICH GCP(R3) concepts will organize Record Types

The CDISC TMF RM used the term artifacts and sub-artifacts

Organizations will need to start thinking and planning NOW about the processes required to generate, manage, and demonstrate compliance with the new records types.

Organizations will get the first look at the new record types when the TMF Standard Model is released for community review in 3Q26.

Organizational Preparations

Process Design

- How new records are created, reviewed, finalized, retained, and made inspection ready

SOP Redesign

- Creation and control of record that demonstrate oversight, data governance, technology use, service provider management, and risk-based decision making.

Oversight

- One of the largest areas of impact.
- R3 places significant emphasis on sponsor oversight, including out-sourced activities, computerized systems, data integrity.

The future TMF must show not just WHAT happened, but WHO was accountable, HOW oversight occurred, and HOW data and decisions were governed.

The CDISC TMF Standard Model

- Not just more documentation; better evidence
  - Benefits:
    - Improved alignment with regulatory expectations
    - Clearer demonstration of sponsor oversight
    - Better support for technology-enabled clinical studies
    - Improved Service Provider accountability
    - More meaningful inspection-readiness
    - Administrative burden reduction – Reduced retention of records that do not add value
    - Greater consistency across sponsors, CROs and other Service Providers, and Technology Providers

The CDISC TMF Community's Call to Action

The CDISC TMF Community is shaping how the industry operationalizes ICH GCP(R3).

They have already…

- Through their community feedback in 2025.
- Through workgroup involvements that have and continue to contribute their expertise on components of the project such as:
  - Triage Committee, Zone Teams, ICH GCP (R3) and EU CTR, eClinical System, Vendor team, ISF, RWE, Device, Metadata, Management Committee, etc.

They will again…

- CDISC TMF Community's review and feedback of the draft version of the CDISC TMF Standard Model in 3Q2026.

Take with You…

The future TMF is not just a repository of documents rather it an ecosystem that demonstrates how a clinical study was designed, conducted, overseen, and appropriately governed.

The CDISC TMF Community is driving the future.

ICH GCP(R3) has given us the directive. The CDISC TMF Standard will give us the opportunity to make operational.

Thank you

Lisa Mulcahy
lisa.mulcahy@mcllc-tmf.com