The Benefit of adopting the eTMF Reference Model

Presented by Morten Nielsen, Principal Consultant, Epista Life Science

Meet the Speaker

Morten Nielsen

Title: Principal Consultant

Organization: Epista Life Science

20+ years in life science industry.

From 2005-2022 I was part of the leadership team in Global Clinical Operations and Head of several departments (Clinical Data Management, Clinical Trial Supplies, Clinical Administration, Clinical (and R&D) Systems departments).

Currently a Principal Consultant at Epista Life Science serving Biotech and Pharma clients with strategic and tactical advice on Clinical Development and IT systems roadmaps, selection and implementation.

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.*

- *The author has no real or apparent conflicts of interest to report.*

Agenda

1. Why eTMF standards are important
2. Exploring the pitfalls and risk of not having a standard for documentation
3. Benefits of having the TMF Reference Model implemented
4. Further utilization of the TMF Reference Model

Why standards are important

Gaining structure to benefit patients

Standards provide confidence

- Standards have been around in for many years in various industries
- eTMF standard provide confidence internally and externally
  - Framework that fits most pharma and biotech companies
  - It is easy to communicate
  - Provides reassurance that there is an inventory of the deliverables and supports processes to uphold the standards

- Standards mitigate some risks
  - Creative filing (in theory…☺)
  - And set foundation for better designed processes and tools

Regulators are expecting structure

ALCOA+

Attributable	Complete
Legible	Consistent
Contemporaneous	Enduring
Original	Available
Accurate	

MHRA FAQ for TMF:

"It is essential to have a suitable indexing system in place for the TMF. This ensures that the documentation is appropriately sorted and filed, which facilitates audit, inspection and trial management".

ICH E6 R3 (Draft):

"Records should be identifiable and version controlled, and should include authors, reviewers and approvers as appropriate, along with date and signature (electronic or wet ink), where necessary".

"The storage system(s) used during the trial and for archiving (irrespective of the type of media used) should provide for appropriate identification, version history, search and retrieval of trial records".

MHRA GCP Inspections Metrics Report

Major findings related to "Recording Keeping/Essential Documents" are top-scoring in 2018-2019-2020

Pitfalls and Risks

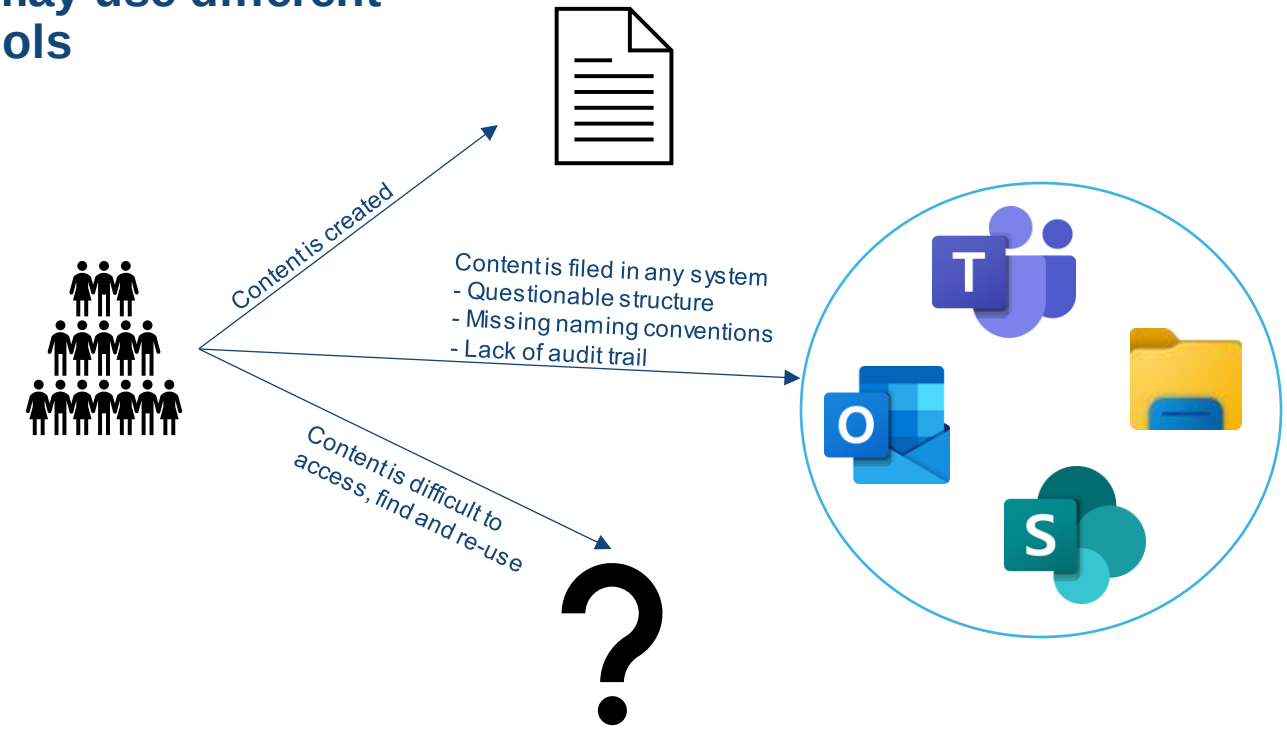
Sharing of structure and best practise

Not having a standard could be expressed by procedures and instructions being:

- **Less intuitive**
- **Less “absorbed” in the organization**
- **Less fit-for-purpose internally as well as with external parties**

Multiple systems & tools for TMF content

Organizations may use different systems and tools



The Ultimate Risk and Pitfall

“A critical document was missing in our submission; this caused a delay for our approval”

CEO of Biotech company

Regulatory inspection result in major and critical findings for records management.

This require significant process updates and resource demanding TMF updates, re-filing and potentially a follow-up inspection.

The even more likely Pitfalls and Risks

"When I need a document from another project, someone sends me a link – I usually cannot access the file."

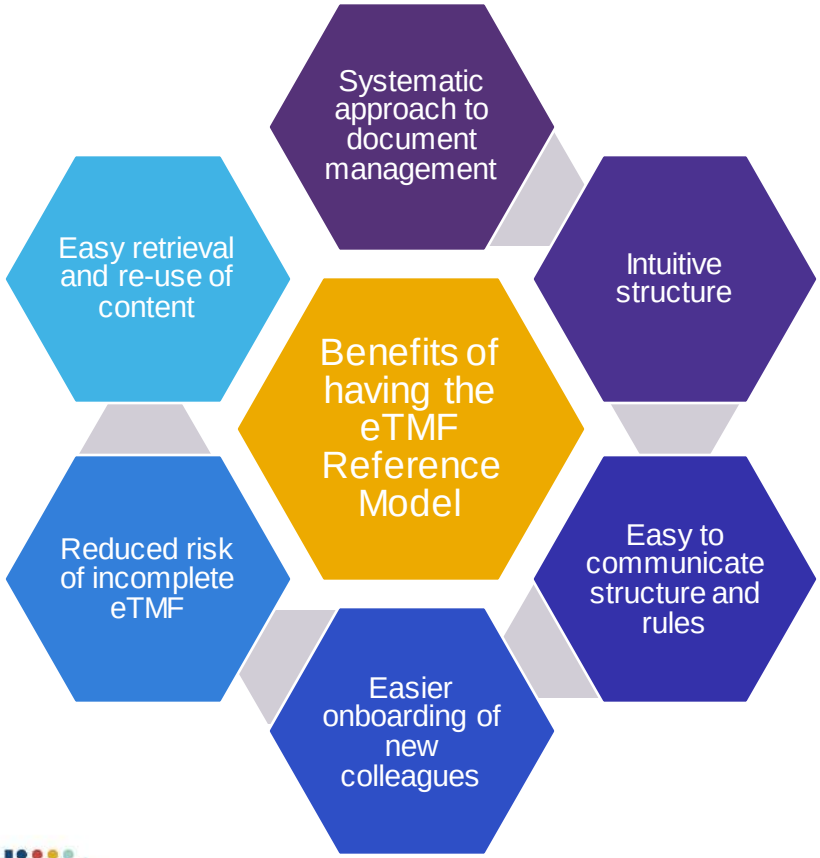
"Working with CROs is cumbersome, because we spend so much effort in translating and mapping our TMF requirements – every time."

"I'm always unsure if I select the right version… or if someone has created a new version somewhere else…"

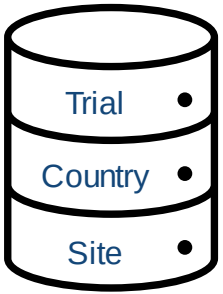
"I really don't have any oversight… we are not aware of the completeness until the trial is to be closed and archived."

Benefits

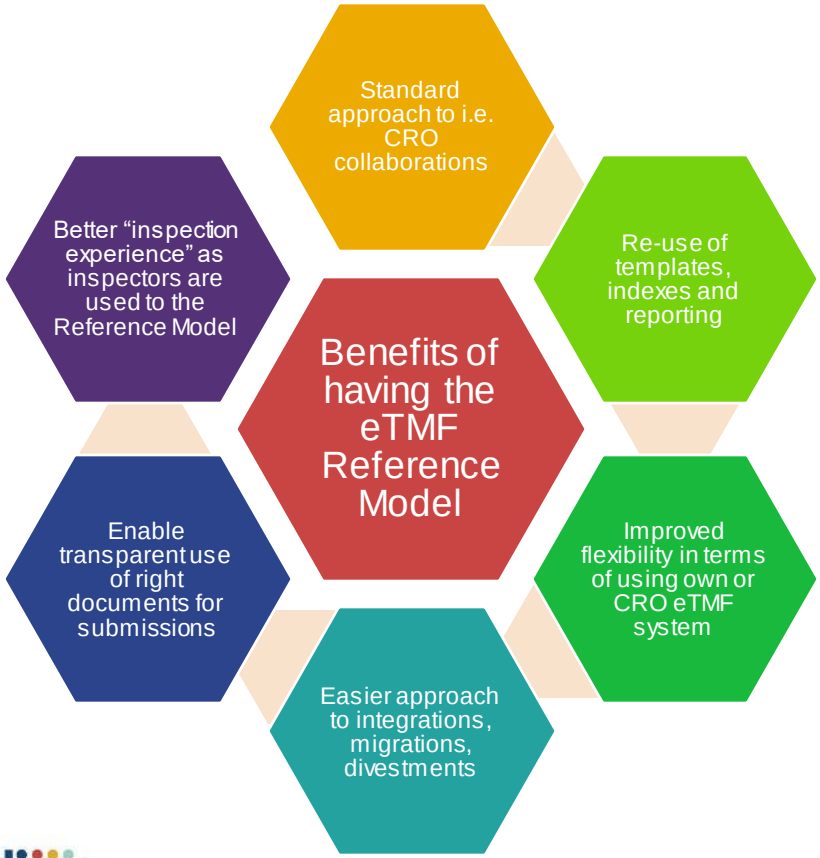
Benefits – within the organization



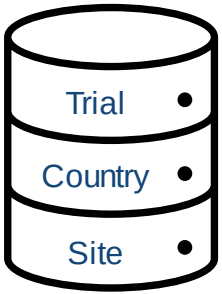
The eTMF Reference Model can be implemented in most modern eTMF management systems



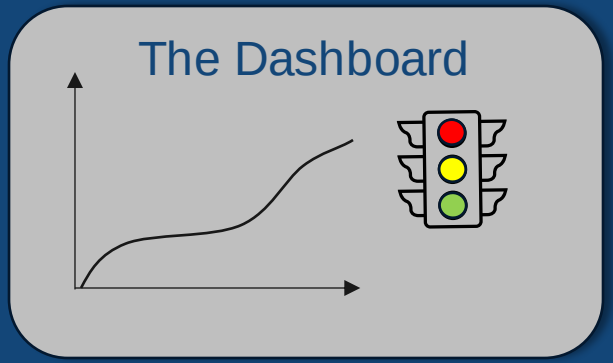
Benefits – outside the organization



Automated document exchange is feasible when using the eTMF Reference Model → enhanced with similar document management systems



Further Utilization



Advanced reporting

Bridging data from an eTMF system with CTMS data and the eTMF Reference Model enables sophisticated reporting.

Reporting can account for expected documents; predict changes to expected document lists and ensure that you have an up to data view on completeness.

Bridging with data from other document management systems creates full visibility of all TMF documents.

- Regulatory affairs repository
- Safety documentation
- ERP/batch documentation
- Quality repository for CAPAs, deviations, audits etc.

!!! You must be smart to avoid manual updates to expected document lists !!!

Summary

- Avoid the pitfalls!
- Implement the eTMF Reference Model to get the:
  - Best alignment with industry and regulatory expectations
  - Best setup to ensure compliance and completeness of your eTMF
  - Best foundation for improved external collaboration
  - Best model for pushing data driven decisions for eTMF

Thank You!