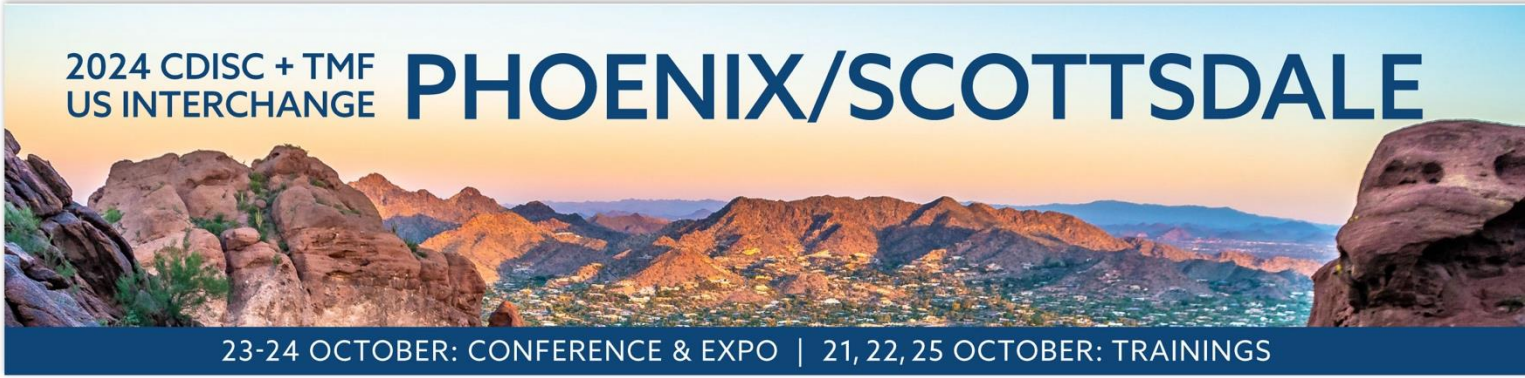


# TMF Sub-Repositories

Debra Wells, Novartis
TMF Process & Standards Team Lead

# Meet the Speaker

## Debra Wells

Title: Team lead, Process & Standards

Organization: Novartis

Debra is committed to the holistic maturity and evolution of the Trial Master File, creating the highest quality and inspection readiness with a focus on cross functional collaboration.

She has over 20 years of experience in pharmaceutical including TMF operations, process design and improvement, simplification, and pharma clinical system implementations.  Her contributions span mid- to large-pharma organizations, including Roche, Eisai, Bayer and currently, with Novartis.

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# Disclaimer and Disclosures

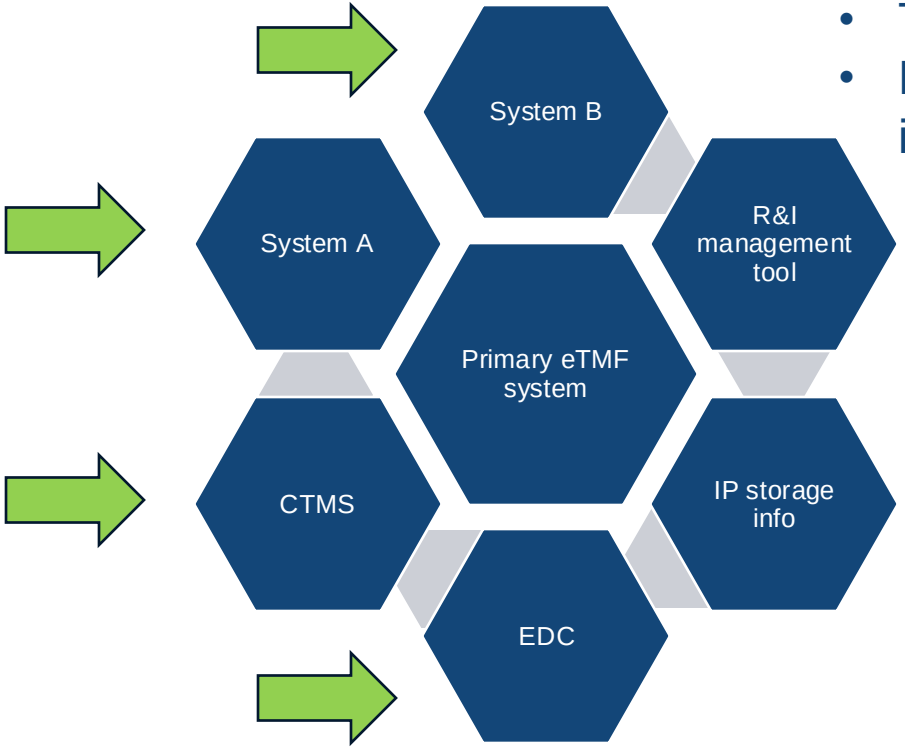
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The opinions expressed here belong solely to me and do not reflect the views of my employer / Novartis*

# Agenda

1. What is a TMF sub-repository?
2. Weighing the benefit
3. Considerations
4. Q&A

# What is a TMF sub-repository?




- No integration
- Total integration
- Hybrid (some integration)

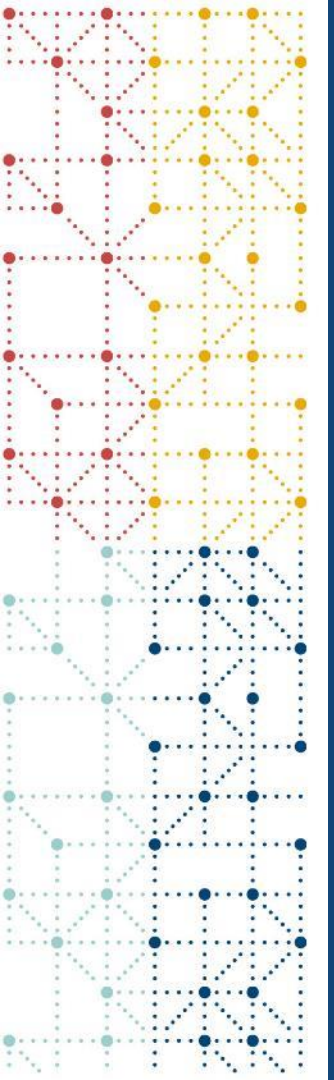
# Unavoidable?

## The trade-off

In order to take advantage of emerging sophistication of specialized tools

- Increase quality
- Can better fulfill the needs of the operational area because they are dedicated to a function, contributing to quick to market
- Is sometimes perceived as a win-win,

convenience and full features



# Weighing the Benefit of Sub-repositories

# Weighing the Benefit

Adopting a sub-repositories is a long term investment of cost, continual monitoring and careful assessments of changes/upgrade to either the Primary and sub-repository.

# Integrated versus non-integrated

**Integrating the sub-repository to the primary enabling records flow into the eTMF automatically is the best long-term approach. Although costly and time consuming, integrations can provide:**

- ***Advantage of using keen features yet the primary eTMF application remains the single source of truth***
- ***Eliminates the clumsiness of having multiple systems/logins during an audit or inspection***

# Integrated versus non-integrated

**Not integrating the sub-repository to the primary requires other 'pointers'**

- ***Signpost or record pointer, filed in the TMF at the record location, indicating where the record can be found***
- ***Some organizations use the TMF Filing Plan to indicate what the intended location of a record***

# What is your experience?

**Integrated versus Non-integrated?**

**Hybrid?**

**Pointers?**

# Considerations

# Considerations

- Understand the perceived benefit
- Establish a governance body that can assess the factors to make a final decision
- Establish a process to continually monitor impact of changes, either at the primary application or the sub-repository application
- Establish a comprehensive checklist and process to assess the sub-repository initially for fitness and re-qualify periodically

# Considerations

- Recognize that a sub-repository is an additional point of failure
- Verify GxP qualification (noting any accepted exceptions)
- Evaluate the dependency of the eTMF on the auxiliary data. E.g., a vendor or lab contract may have less impact than a study risk management tool

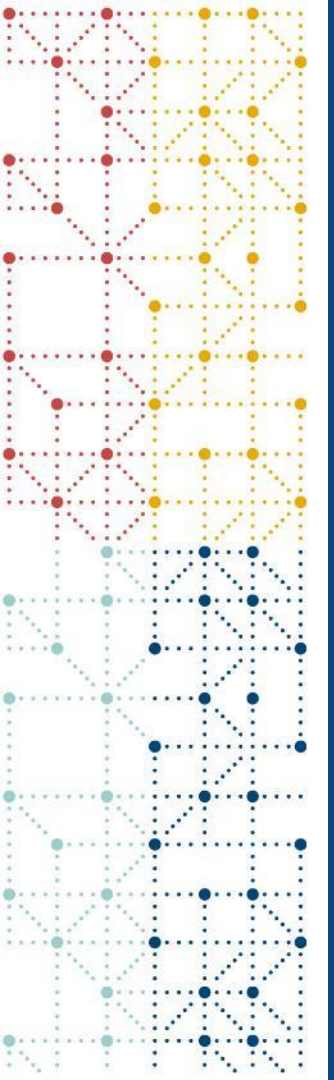
- Alignment of the process around filing the records
- Training of end users (needed for each sub-repository)
- Training of technical or monitoring team. Even the update of a metadata format that goes undetected can cause havoc.

# Considerations

- Managing legal holds

- Long term archiving is established for the sub-repository to support the eTMF archiving strategy

- Clear identification of the TMF records to be stored in the sub-repository and the metadata being stored
- HA training and accounts
- How will TMF review be done, as the sub-repository records need to be reviewed
- Inspection support from the sub-repository technical staff



# Q&A

# Thank You!

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