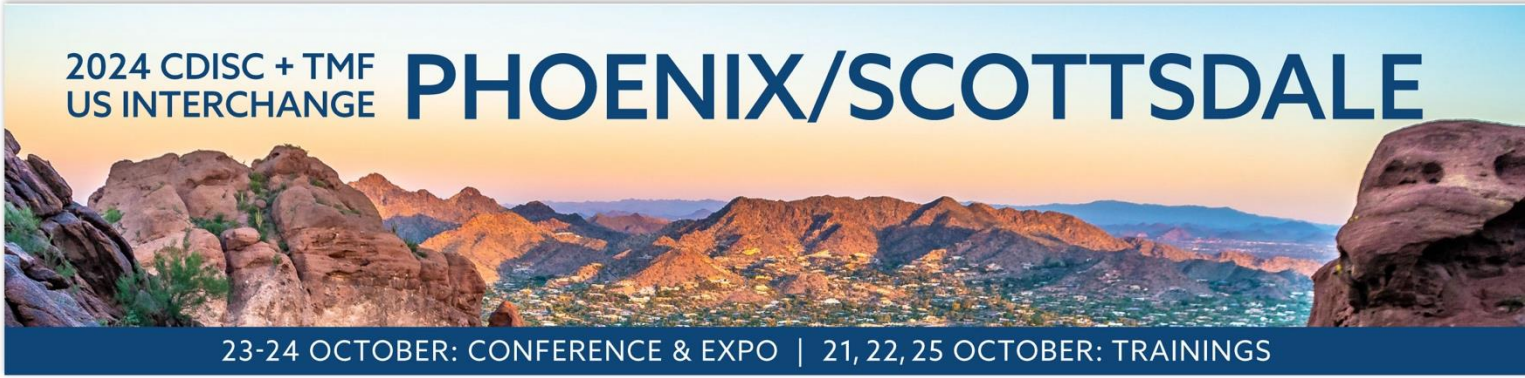

Streamlining the TMF Reference Model for Optimal Clinical Trial Document Management

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Agenda

1. Benefits of the TMF Reference Model and Standardization
2. Implementing the TMF Reference Model: Gilead's Approach and Challenges
3. Future Opportunities

Streamlining the TMF Reference Model

Importance of Industry Standards with the TMF Reference Model

Gilead's Approach to Optimize the TMF

Challenges and Outcomes

Considerations for the Future Reference Model

Benefits of the TMF Reference Model

The TMF Reference Model is consistently evolving based on industry input.
Version 4 aims to progress towards a formal standard that can enable interoperability.

COMPLIANCE

Ensure TMF completeness, no critical documents are overlooked in the trial process

EFFICIENCY

Expedite system and process implementations

Enable streamlined audits and inspections

ADAPTABLE

Tailor the model to meet specific needs of the product portfolio and differences in clinical trial designs

STANDARDIZED

Enable standards across the industry for TMF Artifacts and Study Milestones

Key Aspects: TMF Artifacts categorized in detail, Events and Descriptions defined for Study Milestones

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Benefits of Standardization

Common Language

Standard terminology facilitates communication between Sponsors, CROs, and Regulatory bodies.

Efficient Partner Collaboration

The reference model streamlines work with partners and simplifies integrations during acquisitions and divestitures.

Improved Inspections

Standardization helps inspectors familiarize with setups quickly, reducing training needs and audit complexities.

Prepare for Digital Advancements in Industry

TMF standardization and quality are key prerequisites to enable benefits from digital protocols and automations.

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Implementing the TMF Reference Model

Initial Implementation

Initial eTMF systems and processes expanded on the TMF Reference model to meet business needs

1

Overcomplication

Issues were identified for the Master Index, Change Control, and Data Quality

2

TMF Simplification

Gilead is currently conducting eTMF projects to reduce overcomplication and align with industry standards

3

Future Growth Strategy

The roadmap includes continuous improvement strategies to drive efficiency and compliance

4

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Challenges Leading to Simplification

Master Index

- The Master Index evolved into a process dictating document that could not satisfy all situations
  - i.e. translation requirements, approval workflow, planned document generation
- Size and complexity of the Master Index excel file made it difficult to navigate / use effectively
- Working with the Master Index document outside of the eTMF was cumbersome
- Excessive data points led to confusion and reduced efficiency in document retrieval

Change Control

- Change control was limited in excel, necessitating the creation of separate worksheets to capture details of changes
- Keeping all fields updated became time-consuming, potentially compromising data quality

Approach to Optimizing the eTMF

Simplify the Master Index

Implemented strategies to optimize the TMF Master Index to improve data organization, accessibility, and compliance. By fine-tuning the index structure and processes, sponsors can enhance overall data management efficiency.

Define Milestones

Establishing clear milestones provides a structured framework for managing the TMF Master Index. Definitions from the reference model were used to guide implementation decisions.

Specify Expected Documents

Defining the expected documents within the TMF Master Index helps ensure completeness and accuracy of data.
The reference model was used for an initial mapping of expected documents based on milestone definition.

Partnership Strategy

Gilead is taking a partnership approach to ensure stakeholders stay focused on what they do best, and industry best practices are followed.

Life Science Organization
Business and portfolio expertise

Solution Provider
System and technology expertise

Services Provider
Strategic advisory support for industry best practices

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Outcomes

Overall goals: improve long-term scalability, standardization, efficiency, and data quality within the eTMF

1 Index Simplification

Process related guidance was removed from the Master Index. Guidance on document ownership and clear instructions on filing organization were added.

2 Master Index Automation

The Master Index will be integrated into the eTMF. Currently approved TMF Master Index as well as all index versions created within the eTMF are easily accessible.

3 Automated Change Control

A controlled Change Request submission via system user roles will be implemented within the eTMF. Submission and impact assessment(s) will be completed within the eTMF.

4 Expected Documents and Milestones

Expected Documents and Milestones will be implemented alongside CTMS. This will improve quality and completeness processes and enhance metrics.

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Key Takeaways

Balance is Key

Strive for a balance between comprehensive data capture and system efficiency.

Adapt and Evolve

Regularly review and adjust your TMF model to align with new regulations and IT systems.

Standardization Benefits

Embrace standardization to improve collaboration, inspections, and overall trial management.

Future-Ready Approach

Prepare for upcoming changes in data flow and integration across clinical trial processes.

Future Opportunities

Implementing the TMF Reference Model is a preliminary step to enable sponsor companies to benefit from global data initiatives.

Digital Data Flow Initiative

Initiatives with ICH, CDISC, and Vulcan FHIR will standardize terminology and improve data exchange.

Protocol Integration

Future M11 standard protocols will enable seamless information flow, reducing duplicate entries.

Opportunities for Digital Automation in Clinical Records:

- Automated Milestone detection based on protocol data
- Mapping protocol elements to essential documents
- Real-time updates
- Data-driven compliance
- Interoperability with TMF systems

Thank You!

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