



Breaking the Silos: TMF Integration across the Trial Ecosystem

Presented by Ricky Lakhani, Chief Product Officer
PHARMASEAL



Meet the Speaker

Ricky Lakhani

Title: Chief Product Officer

Organization: PHARMASEAL

Accomplished product management leader with over 17 years of experience specializing in the life sciences and technology sectors. Ricky's expertise is in developing and launching innovative software solutions for clinical trials. Throughout his career, including key roles at Amgen, Roche, and Medidata, Ricky has consistently driven product innovation and growth by effectively bridging the gap between life sciences and technology. His successful track record demonstrates a strong commitment to advancing the industry through influential technology solutions.



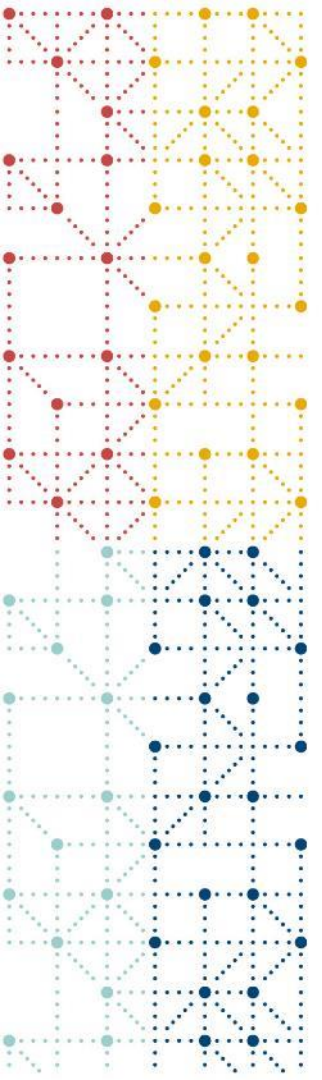
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Agenda

1. Evolving role of the eTMF
2. Interoperability challenges, key gaps & business process hurdles
3. Strategic considerations
4. Turning the TMF into an active asset

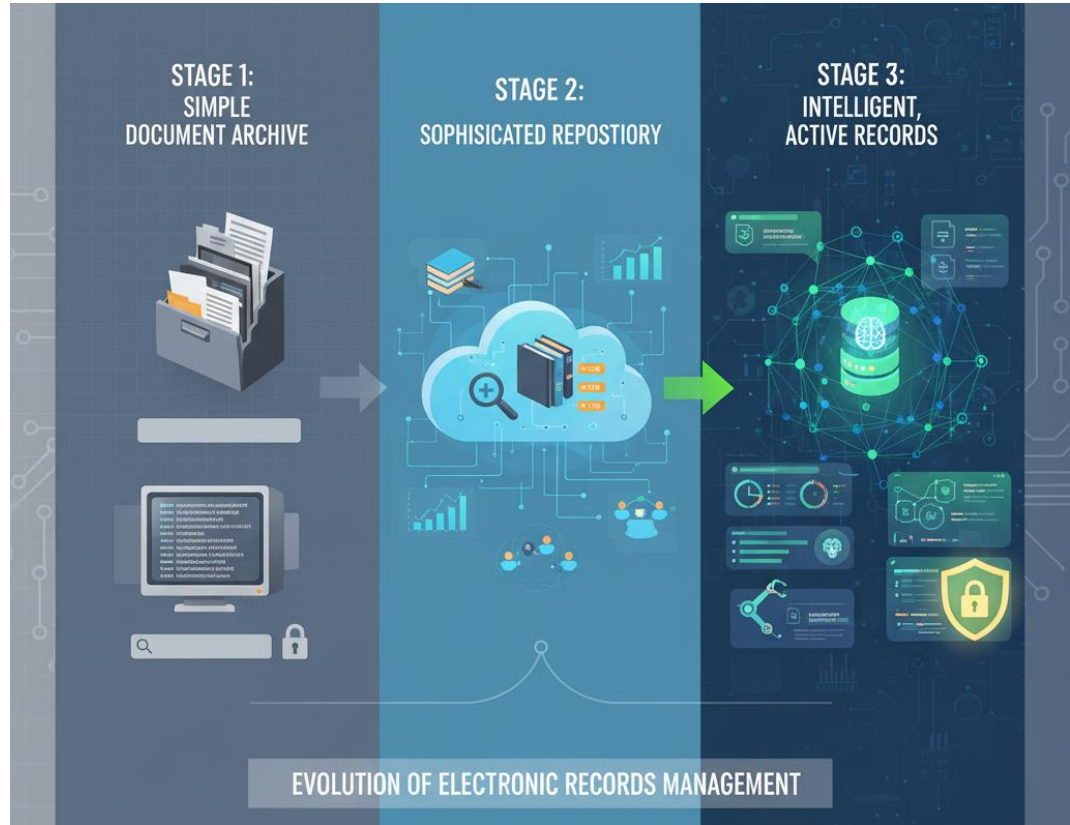


Introduction and Problem Definition

Understanding the shift from a passive archive to operational challenge

The Evolving Role of the eTMF From Passive Archive to Intelligent Repository

- From static archive to essential operational tool
- “Intelligent” repository
- Real-time oversight



The Interoperability Challenge & Key Gaps

TMF content is fragmented which has consequences...

- Content exists in multiple systems
- Leads to:
 - Duplicate effort
 - Inconsistent data
 - Manual reconciliation
 - Compliance risks
- Gaps include:
 - Inconsistent metadata
 - Asynchronous audit trails
 - Lack of automation



Business Process Hurdles of Fragmented Systems

- Manual data duplications
- Inconsistent data and errors
- Inefficient workflows
- Lack of real-time oversight

The Cost of Disconnected Systems.

Fragmentation is not just a technology problem; it creates specific, costly business process challenges that hinder efficiency.





Strategic and Operational Solutions

Selecting systems and embracing foundational standards

Strategic Considerations for System Selection

Single Vendor vs. Multi-Vendor Platforms

- Affordability
- Functionality
- Sourcing strategy
- Degree of interoperability sought

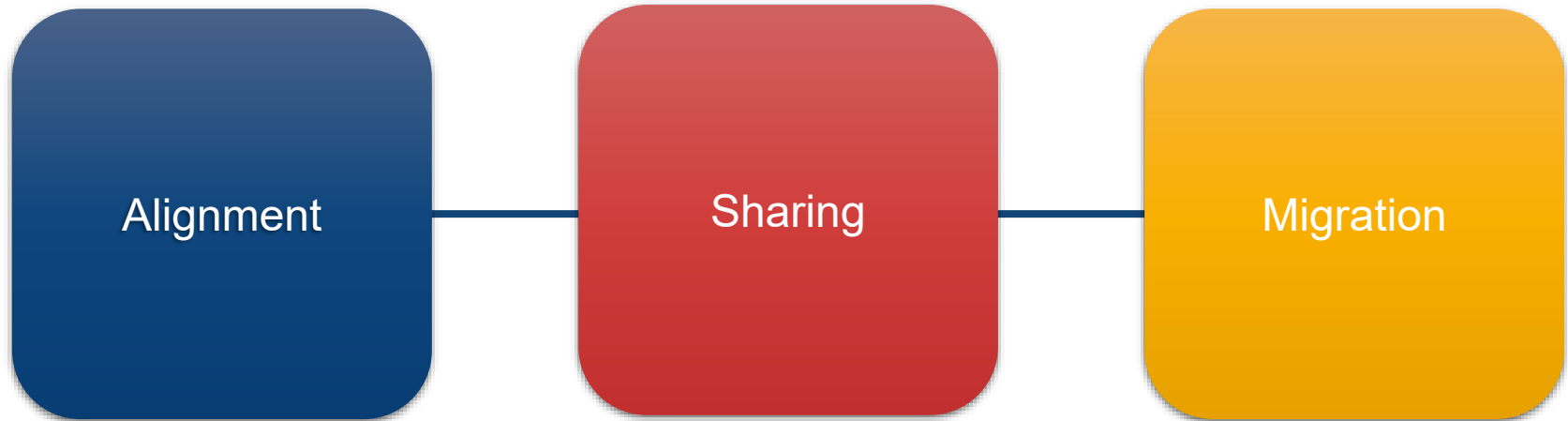


DATA STANDARDS: THE PATH TO CLARITY



Standardizing Interoperability with TMF Models

The Role of Standards





The Future Vision

Data-centric convergence and the rise of an intelligent TMF

The Future of TMF: A Data-Centric Approach

- Intelligent collaboration
- Structured content
- Data-centricity
- Convergence

TMF and the Future

The TMF will become a key component in linking source content to final regulatory outputs as standards evolve toward even more structured data.



The Role of AI in the TMF Ecosystem

Value

- Automated document processing
 - Proactive quality control
 - Intelligent insights
- Enhanced searchability

Challenges

- Data quality dependency
 - Validation
 - Explainability
- Integration complexity



Summary and Call to Action

Transforming the TMF into an active asset

Turning the TMF into an Active Asset

- Positioned as an active part of study execution
- Leverages standards
- Unified and not just integrated
- Intelligent collaboration

Key Takeaway

By leveraging interoperability standards and strategic system integration, organizations can transform their eTMF into a living, active part of clinical trial success.





Thank You!

Ricky Lakhani, Chief Product Officer

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