



Driving Efficiencies with Focus on Quality





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Takeda's TMF Evolution

Define Expectations for TMF Health Across Models

Establish Clear Roles and Accountabilities

Implement Agile, Risk-Based Approach to Monitor TMF Health

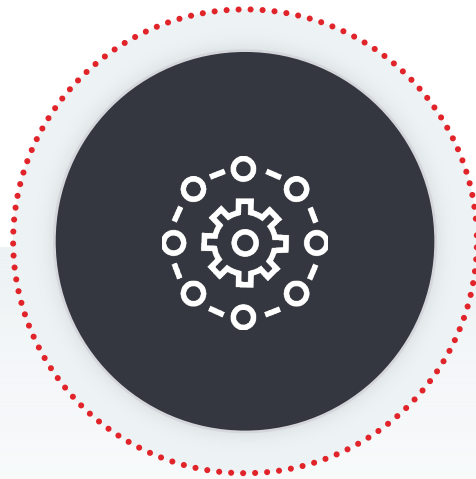
Leverage Technology and Automation to Drive Quality Innovation

Takeda's TMF Evolution



2015

CRO eTMF platform for combined filing; Takeda and CRO documents in separate systems



2017

Takeda eTMF platform implemented



2019

Takeda eTMF with increased quality oversight



2020

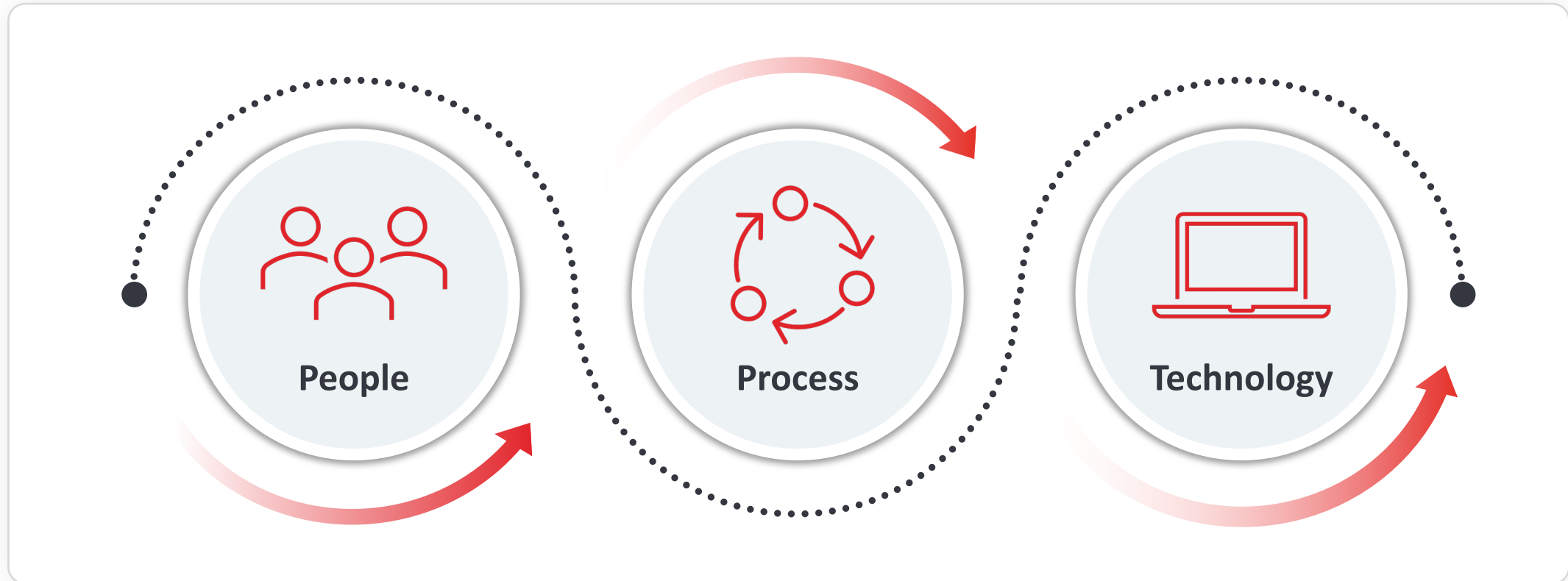
Migration of legacy models to Takeda eTMF

eTMF Operating Model Depends on Quality Oversight Expectations



	BENEFITS	POTENTIAL CHALLENGES
CRO Platform	<ul style="list-style-type: none">• Reduces the number of systems and creates transparency to allow for focus on quality	<ul style="list-style-type: none">• Sponsor reporting, segregation of oversight documentation, and configuration changes• Partner agreements for post-study access for inspections
Sponsor and CRO documents in separate systems	<ul style="list-style-type: none">• Allows each party to follow their processes for overseeing TMF quality	<ul style="list-style-type: none">• Restricted sponsor view of oversight content• Complexity in ensuring TMF quality oversight across two systems
Sponsor All-in Platform	<ul style="list-style-type: none">• Enables sponsor control and quality oversight throughout trial• Ensures consistency in managing TMF content• Drives holistic sponsor view of TMF health	<ul style="list-style-type: none">• Guidance to bridge CRO and sponsor SOPs• Model assumes limited use of secondary systems

Aligning People, Process, and Technology for Quality



People: Define the Internal and External Teams



People: Build Accountability Framework



1

Use TMF operating model to drive oversight approach from study start

2

Develop TMF governing documents to provide clarity around operating model

3

Set clear expectations for direct eTMF access for SMEs, along with upload and review responsibilities

4

Use reports and dashboards to drive periodic TMF quality reviews

5

Demonstrate and document sponsor oversight

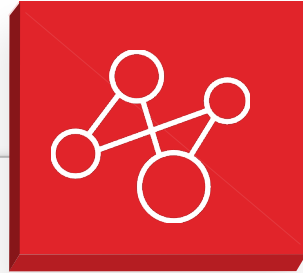
6

Complete end-of-study quality and completeness review before archival

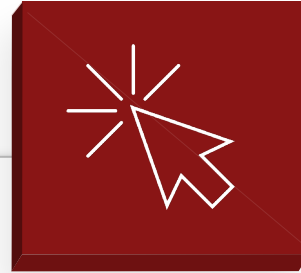


Takeaway: Embed accountability and expertise in study teams and ensure content experts review for quality

Process: Implement Risk-Based Approach to Monitor TMF Health



Use metrics to drive functional area and team priorities



Use reports and data visualizations to identify risk areas



Define risk-based scope to ensure SME focus on critical content

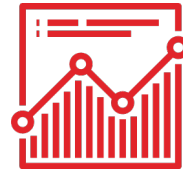


Takeaway: Create visibility to identify risks and optimize operations

Technology: Set Foundation to Drive Quality



**End-to-end
operational data**



**Next-generation
analytics and insights**



**Automation and
innovation**

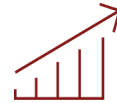
eTMF foundation

Technology: Leverage Automation for Efficiency Gains



Automation Examples

- Provision access
- Auto-classify documents
- File communications in the eTMF



Benefits

- Reduce manual steps for internal and external teams
- Refocus teams on content quality oversight
- Drive time and cost savings



Considerations

- Ensure compliance with global regulations
- Consider methodologies for oversight
- Account for initial learning periods



Takeaway: Moving toward advanced automation drives efficiencies and refocuses teams on quality



Increased compliance with TMF quality reviews



Supported improved inspection outcomes



Improved collaboration with CROs



Reduced time to process access requests for end users and support teams



Reduced document processing time with Veeva auto-classification



Align teams with accountability framework

- Embed accountability and expertise in study teams
- Ensure content experts review for quality (CRO and sponsor)



Build eTMF foundation for further efficiencies

- Leverage insights and analytics to create visibility, identify risks, and optimize operations
- Move toward advanced automation to drive efficiencies and refocus teams on quality

Q&A

