Building Smarter TMF Completeness Processes: A Framework for Improved Oversight

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Meet the Speaker

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Agenda

1. TMF Completeness Challenge
2. Roadmap to Completeness
3. TMF Completeness Solution Overview
4. Key Takeways

TMF Completeness Solution – Sponsor Case Study

A standardized process with a facilitated reporting tool was developed and implemented *to achieve the key compliance requirements for TMF completeness* reporting – in just under 4 months.

Reporting Incorporates Industry Standards with the TMF Reference Model

Future-Ready Approach Prepares for Long-Term Enhanced Automation

Partnerships Ensure Standardization and Ongoing Success

TMF Completeness Challenge

Resource-Intensive Process

Completeness reporting consumes significant manual effort across teams, creating bottlenecks in study timelines.

Complex Study Portfolios

Managing diverse studies with in-house teams and multiple CROs introduces process variability and oversight challenges.

Inspection Readiness Pressure

Ensuring TMF inspection readiness requires continuous monitoring and gap identification across all studies.

Fit-for-Purpose Technology

Out-of-the-box functionality rarely aligns with the nuanced requirements of trial documentation, leading to gaps in oversight across studies and stakeholders.

Roadmap to Completeness

Current State

Compliance risk due to gaps in tools and processes to measure TMF health

Completeness processes are inconsistent across study teams

Heavy resource burden to ensure inspection readiness

Future State

Inspection readiness is maintained with real-time visibility

Completeness reports are available within eTMF

EDLs and Milestones are managed by Study Teams within eTMF

Roadmap to Completeness

Issue: the timeframe from Previous to Future State is an unacceptable compliance risk

Current State

Compliance risk due to gaps in tools and processes to measure TMF health

Completeness processes are inconsistent across study teams

Heavy resource burden to ensure inspection readiness

Future State

Inspection readiness is maintained with real-time visibility

Completeness reports are available within eTMF

EDLs and Milestones are managed by Study Teams within eTMF

- Timeline is dependent on CTMS implementation in the current eTMF system
- Roll-out of the future state to the full study portfolio will be iterative
  - ➢ Timeframe for all studies is unknown

Roadmap to Completeness

Solution: an interim reporting solution is developed to meet business and compliance needs

Previous State

Compliance risk due to gaps in tools and processes to measure TMF health

Completeness processes are inconsistent across study teams

Heavy resource burden to ensure inspection readiness

Interim Strategy

Completeness reporting is available to study teams with actionable outputs

Study inventory reports are pre-configured in eTMF to provide real-time monitoring

Completeness outputs are generated based on Gilead approved EDLs and Milestones

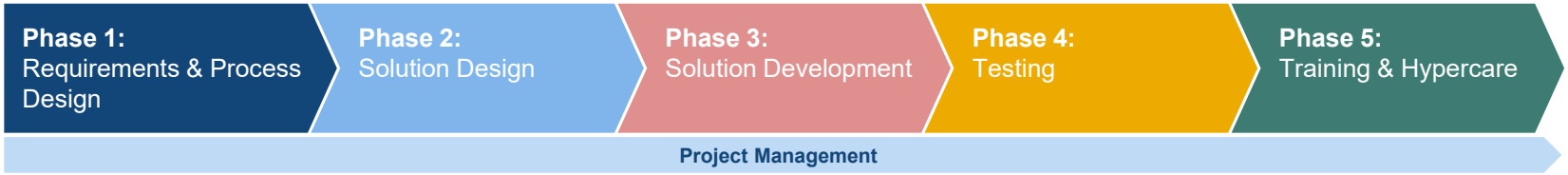
Future State

Inspection readiness is maintained with real-time visibility

Completeness reports are available within eTMF

EDLs and Milestones are managed by Study Teams within eTMF

Our Solution: Core Framework for Success



Requirements

Milestone Drive Requirements:
Automated tracking based on pre-defined study milestones and expected document lists.

Process Standardization:
Integration with Functional Quality Check cycles. Standard governance documentation to support consistent execution and compliance.

Development

Fit-for-Purpose Automation:
Automation limits manual analysis without overly customizing an interim solution.

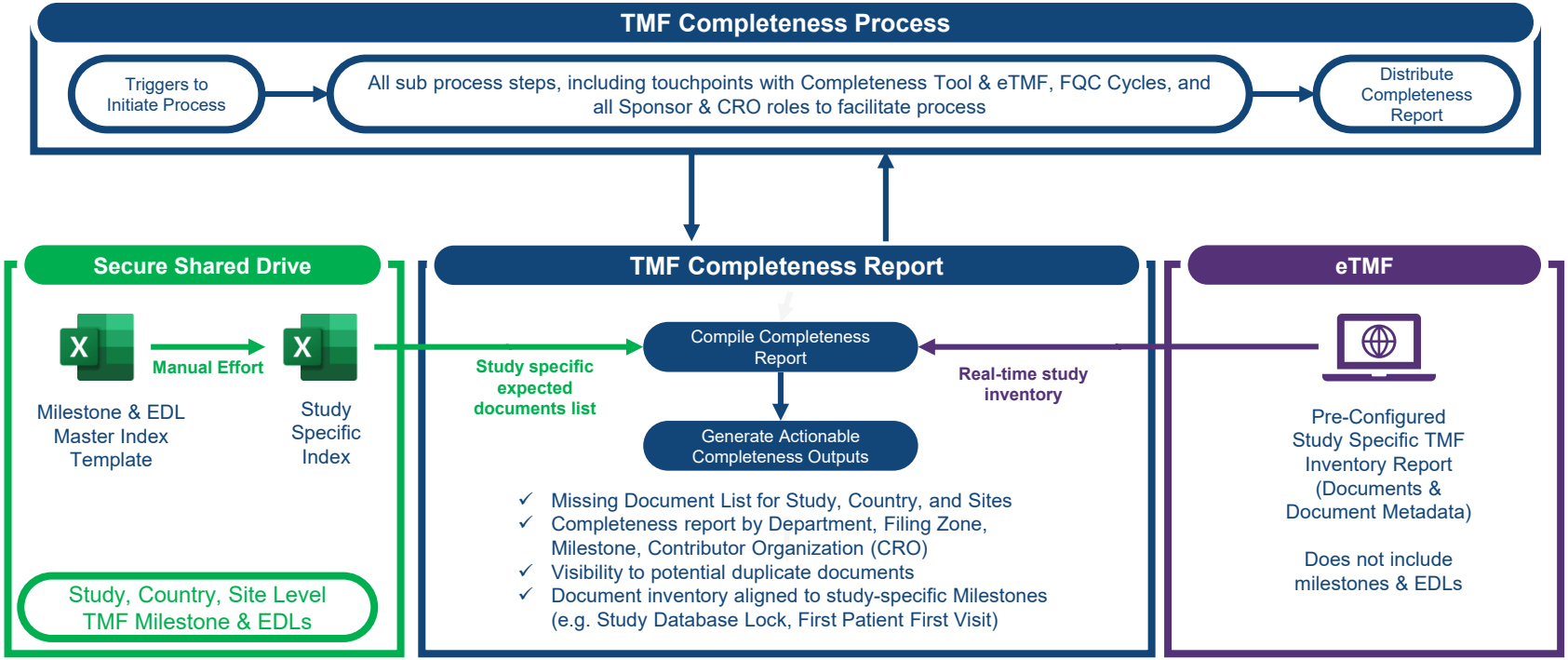
Industry Best Practices:
Source content for real-time reporting (Master Index, Milestone set) is configured based on the TMF Reference Model.

Support

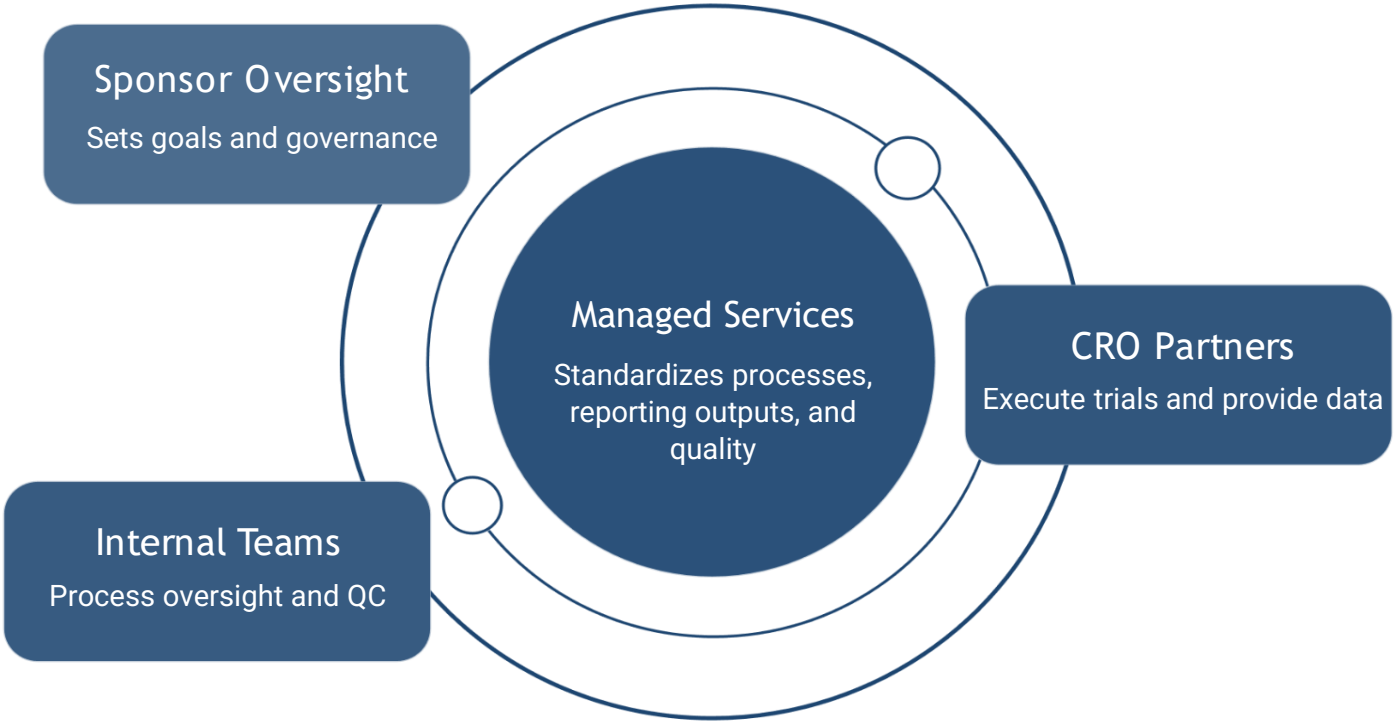
Ongoing Maintenance:
Managed service support team is in place to ensure timely generation of reports and consistent guidance for execution.

Interim Reporting Architecture

The interim reporting toolkit provides actionable insights to TMF Completeness. This achieves the business and regulatory requirements prior to full implementation in eTMF.



Standardization Across Stakeholders



Study Deployment

Pilot Phase

Proof of concept deployment to select studies currently managed by inspection readiness support teams

High Priority Roll-Out

Extended roll-out to Phase 3 studies with adjustments based on pilot phase feedback

Full Portfolio

Full change control and hyper care support for EDL / Milestone toolkit and completeness reporting to all studies

Key Takeaways

Quick Wins

- Achieved standardized TMF completeness reporting within 4-month timeframe
- Improved Study oversight to support inspection readiness and trial best practices
- Measurement is based on industry standards and Sponsor approved Milestones with EDLs
- Future-ready design will enable quick change control to align with system implementations and enhanced automations

Parallel Initiatives for TMF Success

- Data Quality and Remediation Project
- TMF Inspection Readiness SWAT Team
- TMF Metrics: Timeliness and Quality Oversight Reporting
- End-to-End TMF Process Improvement Project

Thank You!