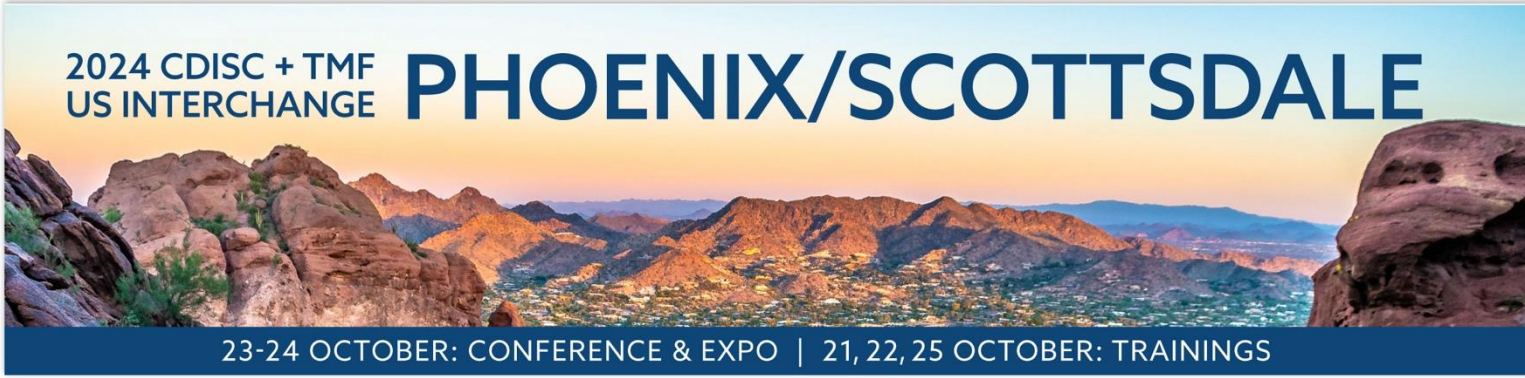

Managing Study TMFs between Sponsors and CROs: Before, During, and After TMF Delivery

5D End of Study Challenges TMF Track – *Panel Discussion*

Meet the Panel Facilitator

Jess Vicari

Title: Sr. Director, TMF Operations and Clinical Systems

Organization: Sage Therapeutics

Jess oversees TMF operations, clinical GxP systems, and operational metrics and reporting at Sage, a brain health company in Cambridge MA.

Prior to her last 5 years in biotech, Jess spent 15+ years delivering TMF and SSU support services as a CRO provider and clinical business solutions consultant, leading global teams of people and dozens of eTMF roadmap initiatives, QC/remediation, digitization and migration projects.

Jess is a technology-driven and regulatory compliance-focused leader who thrives in the details, emphasizes the “why” as integral to successful process engagement and system adoption, and enjoys contributing to our industry’s standardization efforts as a TMF Reference Model Zone Lead.

Meet the Panelists

Colleen Butler

Title: Executive Director, TMF Operations

Organization: Syneos Health

Colleen leads a global team of 500+ TMF experts at Syneos Health. With 20 years of TMF experience at CROs, she has vast expertise in all aspects of TMF including system implementation, migration, managing TMF portfolios for sponsor partnerships, designing optimal TMF FSP models, establishing Risk Based QC, refining TMF Metrics & Key Performance Indicators, developing fit for purpose TMF solutions for sponsors and preparing for regulatory inspections.

John Saviski

Title: Director, Clinical Documentation Operations

Organization: GSK

John co-leads a GSK team responsible for the TMF framework at GSK, serving as Global Process Owner for TMF, building an inspection readiness culture and driving TMF engagement and capability across the business. Prior to GSK, John worked primarily in study management roles across small and large biotech organizations and CROs and has served as TMF point person across multiple regulatory inspections and audits.

Meet the Panelists

Soraya Halligan

Title: Senior Manager, Development Records Management Systems

Organization: Regeneron Pharmaceuticals Inc.

Soraya heads the Development Records Management Systems team at Regeneron Pharmaceuticals, leveraging over a decade of expertise in TMF management. She oversees the global business needs and administration of CTMS and eTMF systems, leading a team responsible for the implementation and maintenance of TMF health metrics, migrations, and integrations.

Princess Barcelona-Martin

Title: Senior Clinical Documentation Manager

Organization: Beacon Therapeutics

With 18 years of clinical research industry experience, Princess has served in key Clinical Operations and TMF Services roles and contributed to the successful startup, conduct, and closeout of Phase I-IV multicenter clinical trials, both in the US and globally. Focusing on TMF management, her expertise encompasses Inspection Readiness preparation and support. Known for her organizational skills and attention to detail, Princess excels in leading teams and coordinating collaborative cross-functional activities.

Agenda

1. End of study TMF challenge scenarios
    1. *Before the transfer – risk assessment and alignment*
    2. *During the transfer – confirmation and contingencies*
    3. *After TMF delivery – integrity in the archive*
2. If we knew then what we know now…
3. Takeaways to derisk TMF delivery

Thank You!

Panel Discussion: **Managing Study TMFs between Sponsors and CROs: Before, During, and After TMF Delivery**

Facilitator: Jess Vicari, Sage Therapeutics

Panelists:

- Colleen Butler, Syneos Health
- John Saviski, GSK
- Soraya Halligan, Regeneron
- Princess Barcelona-Martin, Beacon Therapeutics

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