



## **Enhancing Sponsor & External Service Provider TMF Management through Budget and Scope Alignment**

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# Meet the Speaker

Niamh Smith

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Niamh is an experienced clinical research leader with nearly 20 years of industry expertise, including 15+ years across site, CRO, and sponsor organizations. Through her career, she has led global teams in the strategic delivery of Trial Master File (TMF) management and study start-up. She maintains a strong focus on operational excellence through effective leadership, budget oversight, and process innovation. Niamh is committed to quality and inspection readiness, with a clear emphasis on continuous improvement & optimizing trial delivery to ultimately improve patient outcomes.

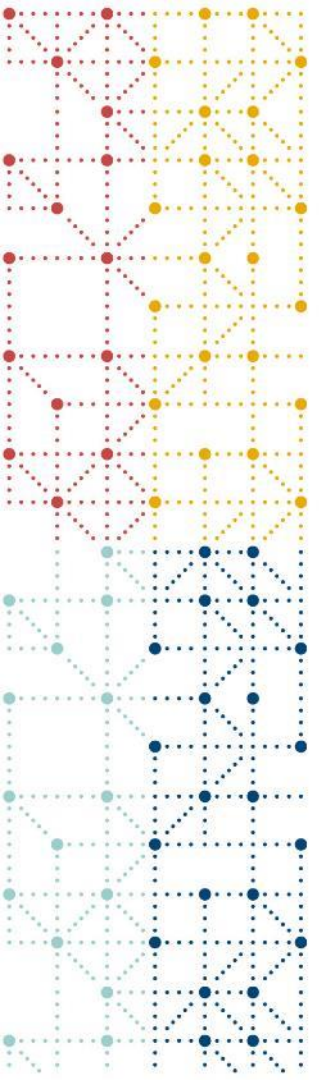
# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*
- *The author has no real or apparent conflicts of interest to report.*



# Agenda

1. Introduction
2. Current Challenges & Common Misalignments
3. Alignment Framework – Defining Scope & Budget Early
4. Preferred Partnership Opportunities
5. Summary



# INTRODUCTION

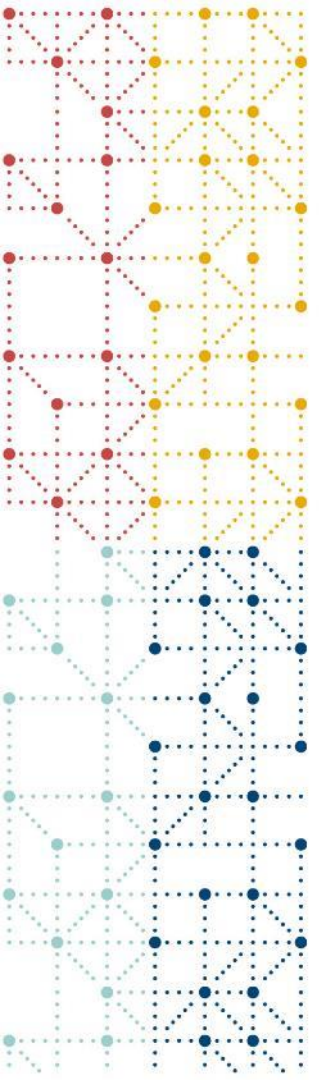
# INTRODUCTION

- Strong Sponsor–External Provider collaboration is essential for effective TMF management
- Outlining required tasks, roles and responsibilities essential to the TMF within the TMF plan is critical as poorly defined scope leads to operational inefficiencies and downstream impacts to inspection readiness
- However, what efficiencies can we gain from stronger collaboration & engagement earlier in the process, aligning before contract execution?
- This presentation will intend to discuss proactive definition of responsibilities, deliverables and costs striving for early alignment to improve operations and inspection readiness.

# Slack App Survey

- Who do you work with- Sponsor, External Provider (CRO), Other?
- Do you participate in the RFI and/or budget review process?
- Budget Line Item: TMF Maintenance
  - How do you define what this means to you?
- What does Inspection Readiness mean to you?





## Challenges & Common Misalignments

We are expecting the TMF to be maintained, I don't understand how that doesn't align to your budget

We are not scoped to review those audit reports; we will need a Change Order

TMF maintenance is listed as a budget line item; clarify why you are now unable to do <insert x> task?

The budget assumptions state Inspection Readiness, but you are not managing periodic reviews?

My definition of completeness is x but you do not perform the task the same; why are we not aligned

This study budget is too costly; please look at cost cutting the TMF as it is higher than competitors

*These are common questions and statements but why do we all hear them?*

# Common Misalignments

- Ambiguity in TMF scope ownership – poorly defined budget assumptions on both parties
- Budget line items often grouped together or misunderstood between parties due to lack of alignment on definitions of TMF maintenance
- “Out of scope” issues arise during active TMF management.
- Resulting in:
  - Reactive v proactive issue resolutions
  - Limited visibility across Sponsor- ESP and impact on inspection readiness
  - Downstream inefficiencies & the inevitable drawn - out change orders



# Alignment Framework

Asking the right Questions & When are we asking them?

# Asking the Right Questions Early



## Detailed Inquiry on TMF Management

Sponsors must ask about the methods and cost structures used by ESPs for effective TMF management.

Does the cost structure equate to the “assumed task”?

Sponsor should have set expectations going into RFP, asking *how*, not *if*, the ESP will maintain the TMF



## Focus on Inspection Readiness

Questions should clarify how inspection readiness and ongoing TMF maintenance will be ensured.

Are the budget assumptions well understood? Does the Sponsor have an expectation checklist or overview for the TMF function?



## Transparency and Alignment

ESPs must ensure Transparency in Budget assumptions & Definitions to avoid miscommunication and align with Sponsor goals.

If tasks are cut as part of a cost saving mechanism, ensure the **downstream impacts are clearly documented and detailed**

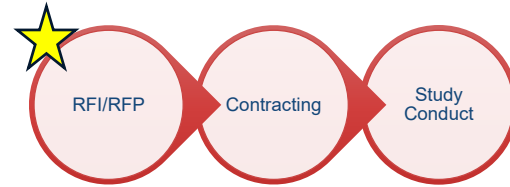
*TMF Teams need to be at the table for budget discussions and reviews*

# Standardized Framework for Alignment

- Challenge, reframe and clarify unclear elements in the RFP request
- **Align Budget Assumptions & Definitions**
  - Is there an industry opportunity that we can build a budget assumption standard, that when we state TMF Maintenance we are all speaking the same language
- Show the financial breakdown clearly and the impact of adjusting expectations and how change orders will be the result if 'assumptions' change
- Budget mapping, align tasks to cost drivers – Doc QC, filing, reconciliation
  - Budget should not be a lump sum; cost breakdown is necessary
- Include contingency planning
  - Amendments, expected increased document volume
  - QTL not achieved, impacts to additional sponsor reviews
- Change control mechanism to reduce CO
  - Process for addressing mid study scope or budget changes

# Why Early Alignment Matters

*If we engaged in a more focused and strategic manner at the RFP and/or early budget negotiation stage, what downstream impacts would we avoid?*



- Clear scope and budget from the outset avoids inefficiencies.
- Clarifies roles, responsibilities and expectations to reduce rework and change orders
- Ensures proper resource allocation & revenue projections
- Enables better forecasting and risk mitigation
- Improves audit and inspection outcomes

# TMF Success

A clearly understood budget scope, allows for a well structured and well defined TMF Plan



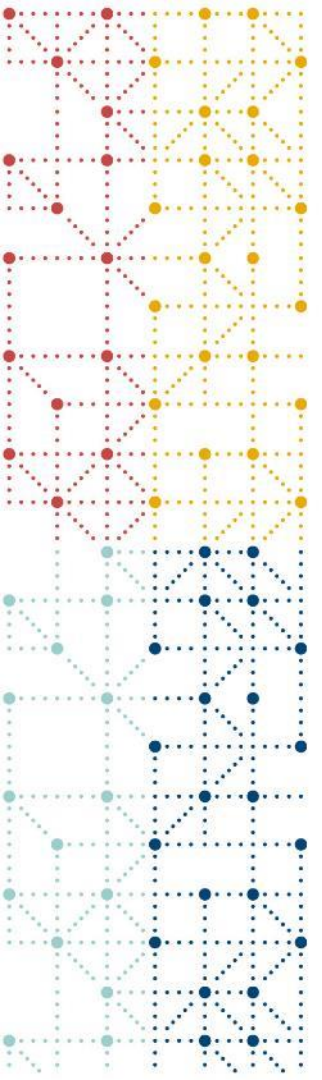
Driving an efficient TMF management model adhering to quality, compliance and inspection readiness.

# Preferred Partnerships

## Partnership Opportunities

- Preferred partnerships can standardize cost structures
  - Apply the same cost structures and definitions across the partnership program rather than continuous reassessment of every bid.
- Consistent TMF management approach across studies. i.e. Program TMF Plan and Study specific index; apply efficiencies across studies
- Reduces duplication, handoffs, and change orders.





# Summary



# SUMMARY

## Early Scope and Budget Alignment

Aligning expectations early strengthens partnerships and reduces unnecessary costs. Alignment is not only operational, it is strategic.

## Streamlined Change Order Process

Clear alignment simplifies and expedites the management of change orders between sponsors and ESPs.

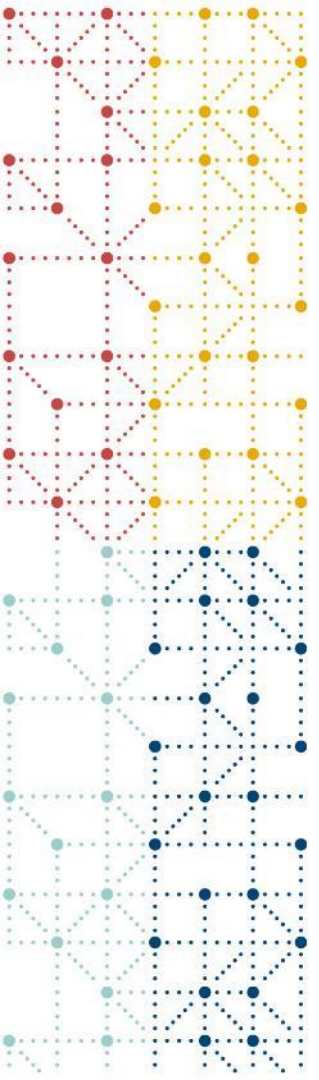
## Consistent TMF Management

A well-defined TMF approach improves quality, compliance, and reduces risk

## Collaborative Framework for Success

Proactive responsibility and financial discussions foster long-term TMF compliance & excellence. Treating one another as partners leads to overall better outcomes

**What impact and actions can you take within your organization?**



**Thank You!**

