



**WHO OWNS THE TMF – SPONSOR OR CRO
DON'T BE SCARED!!**

MONTRIUM TMF WEEK

Tuesday, May 17th, 2022



JP Miceli

Director, Document Management

As the Director of Document Management for Advanced Clinical, JP is responsible for all CRO and FSP TMF activities, and oversees all TMF staff, project management, business development and budgeting, TMF migrations, implementations and system deployment, and acts as the eTMF system administrator and owner. JP's background includes more than twenty years of industry experience at sponsor and CRO organizations, with a primary focus on GxP records management and clinical documentation. JP has been a member of the TMF Reference Model group since 2010, has previously served on the Change Control Board and as the Zone Team Liaison, and currently sits on the Steering Committee.









Leila Ponce

Senior Manager, Regional Clinical Trial Operations, Clinical Systems & Records Management

Leila is a clinical operations professional with over 20 years progressive experience spanning oncology clinical research, trial management, clinical SOP writing, electronic Trial Master File (TMF) management, vendor oversight, and management of validated clinical systems. Leila has a high level of expertise in people management and development, and creating processes governing TMF health and inspection readiness. With strong communication and interpersonal skills, Leila leads cross-functional teams towards decisions in process improvements, scalability, and management of validated clinical systems.



AGENDA

-  Vendor Selection
-  KOM: TMF Expectations
-  eTMF Health Check
-  Oversight
-  Archival
-  Key Takeaways

POLL #1

How is your TMF currently set-up?

- a) CRO owns TMF
- b) Sponsor owns TMF
- c) Hybrid
- d) Don't know

POLL #2

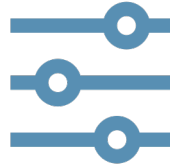
Sponsors: Do you have a company-specific TMF Plan?

- a) Yes
- b) No
- c) Don't know

VENDOR SELECTION



Pre-requisites



Level Setting

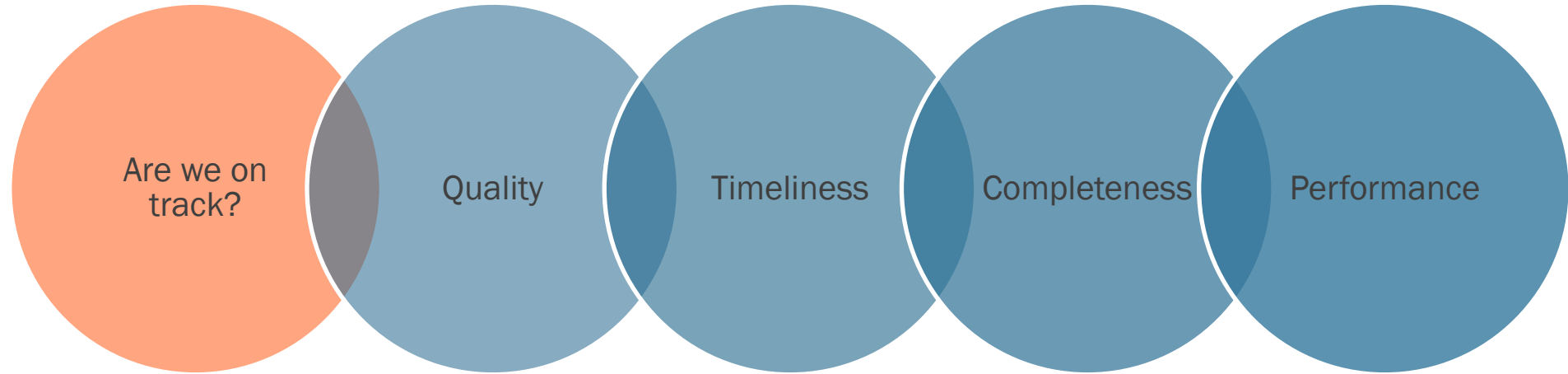


Planning

KICK OFF MEETING



eTMF INITIAL HEALTH CHECK



OVERSIGHT



We're in this
together!

eTMF and Performance Metrics

- It's a plus to have a system that can provide real-time visibility to metrics

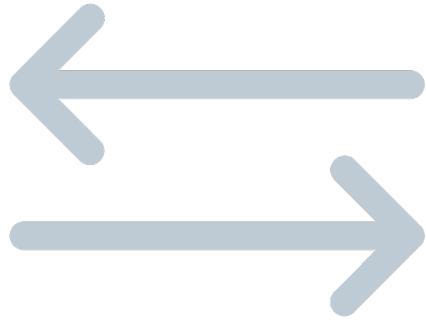
Leverage CRO

- Diverse experience with various sponsors
- Lessons Learned
- TMF management Best Practices

Governance Meetings

- Leadership support is critical!
- Speak in metrics and impact to business
- Ongoing relationship building between CRO & Sponsor

ARCHIVAL/END OF STUDY



TMF Transfer

- Cloud storage
- sFTP
- Compatible system-to-system transfer

Archival

- CRO – not recommended
- 3rd party archival
- Other secured repositories

KEY TAKEAWAYS



Shared Culture of
Quality



Establish
Expectations and
Meaningful
Metrics/KPIs



Leadership Support
for Continued
Maturity/Relationship

