Enhancing TMF Collaboration Across Functions

LMK
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The Collaboration Problem

Why This Matters:

TMF quality depends on consistent contributions from every function. But many teams still don't know what they're responsible for or how to contribute. This leads to confusion, missing documents, and delayed inspections.

How LMK Can Help:

We work with sponsors and CROs to define clear roles, map responsibilities to the TMF Reference Model, and build guidance tailored to each function.

How You Will Succeed:

Your teams will know exactly what's expected, contributing the right documents at the right time—and reducing closeout chaos.

Overcoming Contributor Resistance

Why This Matters:

Many contributors see the TMF as “someone else’s job,” especially if filing isn’t part of their day-to-day. This mindset leads to gaps and delays.

How LMK Can Help:

We create tools like FAQs, how-to guides, job aids, and short video walkthroughs—customized by function—to make TMF filing approachable and easy.

How You Will Succeed:

With accessible resources and less friction, contributors take ownership. Filing improves, quality goes up, and timelines stay on track.

CROs, Hybrids, and Internal Document Chaos

Why This Matters:

Sponsors often hesitate to send documents to CROs, resulting in fragmented TMFs and audit risk.

How LMK Can Help:

We design hybrid TMF models, establish internal repositories that meet 21 CFR Part 11, and ensure alignment across sponsor-CRO boundaries.

How You Will Succeed:

You'll have a clear, auditable structure—even when documents live in multiple systems—and confidence in inspection readiness.

Making the Most of Your Metrics

Why This Matters:

Study teams can't fix what they can't see. Without metrics, there's no way to know which functions are filing on time—or falling behind.

How LMK Can Help:

We build custom dashboards and reports for your eTMF system and pair them with communication strategies to engage every function.

How You Will Succeed:

With clear, role-specific insights and regular trend reviews, your teams will stay engaged and accountable.

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Oversight, Ownership, and What's Next

Why This Matters:

ICH E6 R3 makes sponsor oversight more important than ever. But oversight isn't just about checking—it's about enabling.

How LMK Can Help:

We help you implement risk-based TMF QC plans, define sampling strategies, and document rationale for inspection readiness.

How You Will Succeed:

With oversight plans that scale and a clear story behind every decision, you'll be ready for regulators—every time.

CONTACT US

Have questions or need assistance? We're here to help!

Email: Hello@lmkcrc.com