



10 Red Flags That Your eTMF Needs Attention

Is your TMF signaling bigger issues—ones that impact inspection readiness, team confidence, and study success?

Use this checklist as a quick reality check.

- 1 **Essential documents/records are not available** due to delayed filing.
- 2 Your team **cannot easily identify what's missing** from the eTMF at key milestones.
- 3 You **haven't performed and documented oversight** of the eTMF.
- 4 Your CRO says the eTMF is fine—but you keep hearing about hard-to-find documents.
- 5 The **same quality issues keep appearing** in spot-checks or audits.
- 6 Documents/Records supporting change related to **protocol deviations are incomplete or unavailable**.
- 7 **No reliable way to align key study plans** with eTMF content
- 8 System **lacks proper audit trails to show record/document history and related actions**
- 9 CRO/Vendor **oversight documentation is inconsistent, minimal, or missing**.
- 10 You've raised internal concerns but **lack sufficient evidence to support concerns**.

 **Seeing red flags? Let's talk.** 

Book a free consult with our TMF experts and get clarity on your current risks
—and where to go from here.