The Clinical Vendor Oversight Illusion: Are We Managing Risk or Just Documenting It?

From inspection readiness to inspection steadiness—and the missing governance layer between QMS and eTMF

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Clinical trial sponsors have become adept at documenting oversight. We develop plans, establish governance committees, monitor KPIs and maintain extensive records in the electronic trial master file (eTMF). We have also invested heavily in quality management systems and increasingly sophisticated reporting tools. Yet when an inspection approaches, many teams still face an intensive exercise in locating evidence, reconciling records and reconstructing decisions.

That disconnect raises a question worth examining: have we become better at documenting our intention to oversee CROs than at demonstrating how oversight works in practice?

When does the oversight plan become the finish line?

The familiar sequence begins with considerable effort. Clinical operations, vendor management, quality and functional leaders collaborate with the CRO to draft an oversight plan. Responsibilities are agreed, metrics established,

governance meetings scheduled and escalation paths defined. The approved plan is filed in the eTMF, and attention turns to study execution.

The difficult part, however, is what happens afterward. Are commitments consistently followed? Are performance signals recognized early? Are escalations proportionate to risk, and are agreed actions completed? Most importantly, can the sponsor readily demonstrate the sequence of observations, decisions and follow-through?

Meeting minutes alone do not establish that governance was effective. A dashboard is useful only when its signals inform decisions. An escalation process matters only when issues are acted upon and resolved. This distinction is especially consequential in fully outsourced studies, where clinical operations, outsourcing and quality teams may each hold a different part of the oversight record.

"An oversight plan is a promise. Evidence of execution is proof."

The space between QMS and eTMF?

One of the least discussed gaps in clinical development technology lies between quality management and trial documentation. A quality management system (QMS) supports deviations, audits, corrective and preventive actions (CAPAs) and other formal quality processes. An eTMF preserves essential trial records and provides a structured body of inspection evidence. Both are indispensable, but neither necessarily serves as the operating environment for continuous CRO governance.

Consider a CRO that misses a performance threshold. The issue is discussed at a governance meeting and a corrective action is assigned. Two months later, the same pattern

emerges. Was the original action completed? Was the issue escalated appropriately? Is the recurrence isolated to one study or evident across the portfolio? Does the vendor's risk profile need to change?

Not every performance concern warrants a formal CAPA, and filing meeting minutes does not ensure that an action is completed. Much of the work connecting performance signals, commitments, decisions and outcomes still takes place in spreadsheets, email and disconnected trackers. Some organizations have configured their QMS or eTMF to support parts of this process; the challenge is less the absolute absence of technology than the lack of a consistently connected governance model.

"QMS manages quality events. eTMF preserves evidence. Who connects the decisions, commitments and actions in between?"

ICH E6(R3) and the obligation to demonstrate oversight

ICH E6(R3) reinforces a principle that is particularly relevant to fully outsourced clinical development: transferring activities does not transfer the sponsor's ultimate accountability. Section 3.6.9 addresses appropriate sponsor oversight of important trial-related activities transferred to service providers; Section 3.9.6 addresses timely escalation and follow-up of issues. The guideline also emphasizes approaches proportionate to trial risks.

The practical implication is not simply a need for additional documentation. Sponsors should be able to trace a meaningful line from a performance or quality signal, through risk assessment and governance decisions, to accountable actions and their resolution. Oversight becomes credible when the evidence reflects how the process operated, not merely how it was designed.

The overlooked economics of inspection preparation

Regulatory inspection costs are often discussed in the context of findings, remediation and potential enforcement. Less visible is the operational cost of preparing for an inspection: the hours spent gathering records, reviewing decisions, reconciling information and responding to requests. Experienced clinical, outsourcing and quality professionals are diverted from their normal work, even when the inspection ultimately proceeds without significant findings.

There is also a wider economic consequence when fragmented governance delays the detection or resolution of recurring issues. The EMA's 2024 GCP inspection reporting recorded 335 major and critical deficiencies across 67 CHMP-requested inspections. Published comparisons of FDA and EMA inspections have also highlighted trial management and documentation as recurring deficiency areas.

Research from the Tufts Center for the Study of Drug Development has estimated approximately $40,000 per day in direct Phase II/III trial conduct costs and around $500,000 in average commercial value associated with a day of delayed prescription-drug or biologic sales. These figures do not quantify the cost of weak CRO oversight, and not all delays arise from governance failures. They do, however, illustrate why even modest improvements in issue resolution and administrative efficiency can matter. The industry-wide economic impact attributable specifically to fragmented vendor governance remains unmeasured.

From inspection readiness to inspection steadiness

While preparing for a recent Clinical Maestro webinar, we began using the term "inspection steadiness." It captured a distinction that has stayed with me and inspired this article. Inspection readiness is

commonly treated as the ability to prepare evidence when needed. Inspection steadiness describes an operating state in which governance activities, decisions and follow-up are documented as part of normal work—and can be demonstrated at any time.

In an inspection-steady organization, oversight plans translate into actionable activities; performance and quality risks are assessed in context; accountability is visible; and evidence develops alongside execution. Inspections will always require coordination and judgment, but there should be less need to reconstruct months of oversight retrospectively.

"Inspection readiness is something you prepare for. Inspection steadiness is how you operate."

What AI can and cannot change

The operational barrier has long been the effort required to connect information across systems and functions. Teams collect KPIs, consolidate scorecards, review minutes, track commitments and prepare summaries. Often, the data exists but the connected picture does not.

AI can help identify patterns across studies, summarize governance histories, highlight unresolved actions and surface evidence gaps. A sponsor should be able to ask which significant CRO performance issues occurred over six months, what decisions followed, who owned the actions and which issues remain open—and receive a traceable answer grounded in the underlying records.

This requires more than adding a chatbot to disconnected files. Structured processes, reliable data, permissions, source traceability and human review remain essential. AI

should support accountable decisions, not replace them. Its greater value may be in making ongoing oversight more consistent, rather than merely accelerating the preparation of inspection reports.

Why we built VISION Plus



Having led clinical outsourcing and vendor management functions in pharmaceutical and biotechnology organizations, I have seen how much effort goes into building sound oversight plans—and how difficult it can be to translate them into consistent, demonstrable practice. Governance teams can spend more time collecting information than interpreting it. Performance issues may remain disconnected from quality events, contractual commitments and broader vendor risk.

Those experiences informed our decision to build Clinical Maestro VISION Plus. The objective was not another dashboard or document repository, but a connected environment for the activities that take place between operational performance, formal quality management and the trial record.

VISION Plus brings together vendor qualification, governance activities, KPIs, risk assessments, audits, issues, escalations, CAPAs and follow-up actions. It is designed to complement QMS, eTMF and clinical operations systems rather than replace them.

With Maestro AI embedded in these workflows, the aim is to help teams investigate trends, connect related information and produce evidence-linked governance insights without repeatedly reconstructing the underlying story. We see this as

a pioneering approach to AI-native clinical vendor governance, linking performance, risk, compliance and sponsor accountability within the same operating model.

Ultimately, the ambition is broader than reducing administrative effort. It is to make continuous oversight practical and scalable, so that inspection evidence becomes a natural by-product of well-executed governance.

A better question for sponsors

ICH E6(R3) offers an opportunity to reconsider not just the documentation of oversight, but the way it is performed. Technology can help, but meaningful change also requires clearer accountability and a willingness to revisit familiar practices.

The next time an oversight plan is reviewed, three questions may be more useful than asking whether it has been approved and filed: Is it being followed? Are emerging risks being acted upon? And can the organization demonstrate both without a major reconstruction exercise?

The future of vendor oversight should not depend on being ready for the next inspection. It should depend on being steady every day.

ABOUT THE AUTHOR

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