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# How to Build Effective Clinical Trial Oversight and Leadership

**You win before you start,**
**or you lose before you start.**

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**Biopharmaceutical clinical trial sponsors shoulder both financial and oversight responsibility for their study. While the sponsor's C-suite usually offers some high-level strategic direction and helps with project resourcing, outsourcing partners typically manage the trial's operational aspects. But poor vetting, overreliance on partners, and ineffective collaboration can quickly derail a clinical trial. To stay on time and on budget, sponsors must balance mutual trust with productive "pushback."**

## Traditional Outsourcing Models Often Have a Leadership Void

In a traditional outsourcing model (Fig. 1), the sponsor has limited access to the key individuals working under the CRO project manager. But this structure often hides operational issues, as all communication is funneled through the project manager. While many sponsors believe this is what they want— a hands-off approach that still delivers precise data—they overlook the fact that everyone beneath the CRO project manager has direct, critical interactions with the sites generating and managing that data.

This model often sidelines a sponsor's clinical operations (ClinOps) team, effectively turning the sponsor's trial into the CRO's trial. While this is not inherently negative for sponsors seeking a light-touch approach, it puts even more pressure on (and cedes power to) the CRO's project manager to identify and elevate issues experienced by the team. Weak functional leads (e.g., TMF manager, study startup manager, biostats lead) may go unnoticed or have their mistakes quietly corrected. The sponsor, lacking visibility, then has no way to identify those weaknesses.

When those weaknesses involve people handling trial data, the sponsor is left vulnerable. This is why the sponsor must fulfill three key ClinOps roles during a clinical trial:

1. **Leadership** — Set the trial's strategic direction, design a protocol based on clear project goals, and define a regulatory pathway with an understanding of its operational implications.

2. **Accountability** — Make final decisions, oversee the trial budget, and ensure choices are informed by close collaboration with outsourcing partners.

3. **Collaboration** — Foster productive relationships with the CRO and any other outsourcing partners while maintaining engagement with investigative sites and external stakeholders.

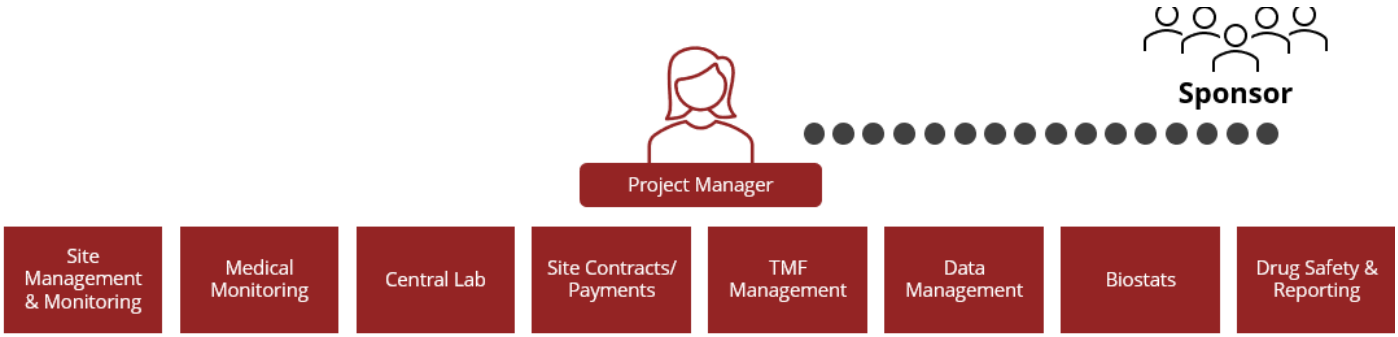


**Fig. 1:** Depiction of a traditional CRO outsourcing model

## A Successful Trial Requires Engaged Leadership

In a more collaborative model (Fig. 2), the sponsor still outsources where needed but maintains direct contact with functional leads. This eliminates communication gaps and enables faster, more informed decision-making. This model also gives the sponsor greater visibility into the CRO ClinOps team, helping identify weaknesses and offering avenues toward course correction (e.g., mentoring).

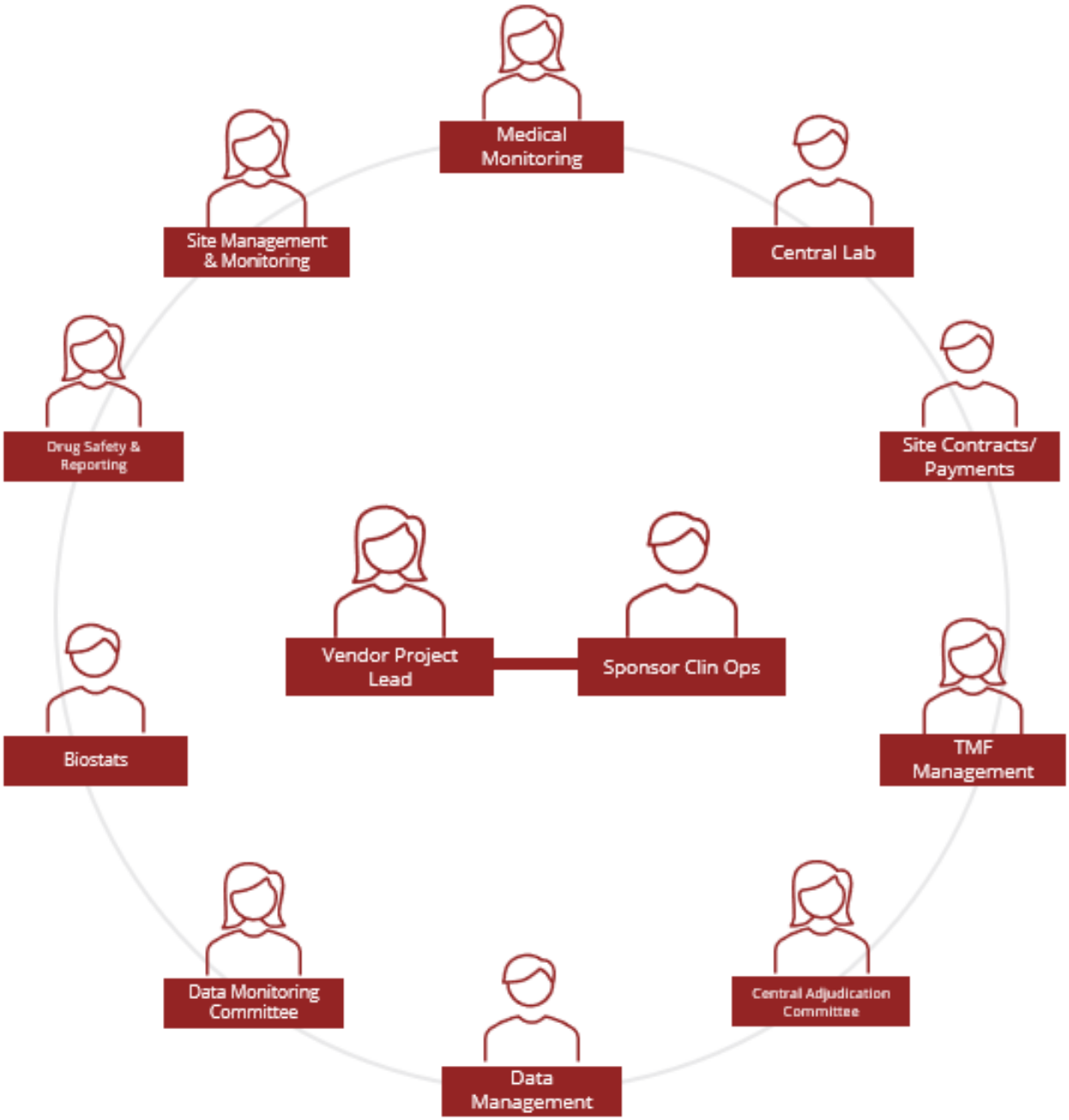


**Fig. 2:** Depiction of a modern CRO outsourcing model that proritizes collaboration between the sponsor and CRO ClinOps teams

In this model, the outsourced team functions as an extension of the sponsor's ClinOps—not just another vendor. This integration is critical: the vendor team should contribute to meetings and understand the sponsor's rationale for its decisions. When this model is applied successfully, the model can flexibly include any mix of functional leads, giving sponsors access to expertise they may lack in-house.

Working side by side promotes collaboration and enables both parties to ask questions about operational or strategic decisions. Ultimately, the model's success depends on mutual trust and clearly defined roles from the outset. Strong partnerships welcome questions, using them to clarify challenges, align priorities, and decide what information is essential to share with each team.

Conversely, a lack of trust generally reflects poor planning. It tends to promote reactive decision-making and delayed issue resolution. A sponsor/vendor relationship that lacks trust and open communication also can damage relationships with sites and key opinion leaders (KOLs), who may be unsure of who is truly in charge.

## Challenges in Sponsor/CRO Relationships

It is vital to address several common challenges in sponsor/CRO relationships to firmly establish the sponsor as the trial's leader:

**Communication** – Open dialogue with all vendors and partners is essential. Ensuring everyone—whether directly contracted or subcontracted, like ePRO vendors—receives the same information creates alignment and enables fast, coordinated action. Clear communication drives execution, especially when multiple parties must act on shared information.

**Misaligned Goals** – Sponsors often withhold key context but still expect CROs to know what they want, how, and when. Goals and priorities are clearer and more attainable when the CRO project manager understands the rationale behind the sponsor's decision-making.

**Issue Escalation** – Escalation protocol can be paradoxical: the sponsor wants the CRO to attempt to solve problems before troubling the sponsor but also may feel the CRO is delayed in solving or reporting those issues. Finding the right balance is key: not every issue requires escalation, but partners should agree on what does. Frequent, open communication naturally surfaces emerging risks and avoids surprise escalations, making it easier to reach solutions along the way.

**Depth of Experience** – Vetting a potential partner's experience extends beyond looking into the CRO organizationally; it means vetting the CRO team assigned to the study. A large CRO may have an abundance of organizational experience but assign less experienced staff, while a smaller CRO may dedicate more seasoned professionals directly to the study team.

Typically, the sponsor is the expert on its product and study objectives, so even a highly experienced CRO will not match the sponsor's internal expertise. When vetting a CRO and its proposed team, a sponsor should gauge the CRO's willingness to learn the study's goals and rationale. Enthusiasm and collaboration can help offset experience gaps.

On the sponsor side, depth of experience means knowing the study's critical variables—especially in complex trials, such as those in rare disease, that may combine multiple objectives due to a limited patient population. Identifying gaps in expertise and bringing all partners into shared discussions helps mitigate risk. Be wary of vendors who resist collaboration, such as a CRO that objects to sharing responsibilities or refuses to coordinate with other vendors.

**Quality of Work** – The quality of a CRO's work often is linked to the frequency and effectiveness of sponsor touchpoints. If the only person the sponsor's ClinOps team talks to at the CRO is the CRO project manager, the former loses visibility into day-to-day operations. Early engagement is essential to set expectations and catch issues before they impact trial outputs.

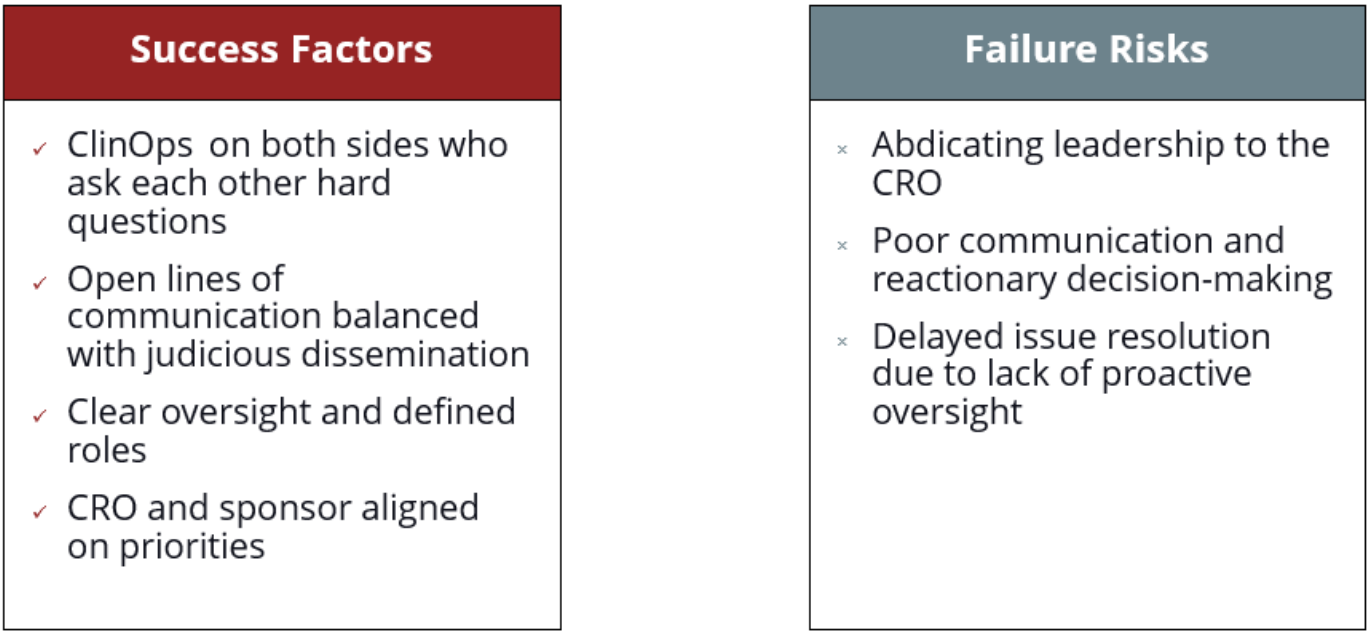


**Fig. 3:** Lessons in trial oversight

For example, sponsors need to closely review early deliverables like trip reports to ensure quality standards are met. Disregarding the importance of early outputs can allow bigger problems to develop. Sponsors should not feel pressured to adopt CRO processes that don't align with their study objectives. If CRO processes compromise quality, the project plan should be revised. CRO resistance to process changes should spark a conversation, not end one.

## Create Clear Internal Processes For ClinOps Oversight

A popular adage relevant to clinical trials states, "You win before you start, or you lose before you start." Sponsors that plan ahead, embracing a decision-making structure and a strategy for the internal ClinOps team, have a better chance at a successful study than those who react to problems as they arise. A well-prepared internal ClinOps team not only drives protocol execution but also guides thoughtful vetting of outsourcing partners.

Every trial will face challenges. Sponsors need partners they trust to understand—and to make—difficult decisions, while asserting leadership both in mindset and in practice. Open communication fosters collaboration, allowing sponsors to lead confidently without micromanaging or neglecting their partners.

To learn more, contact the authors and visit https://inseptiongroup.com.

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