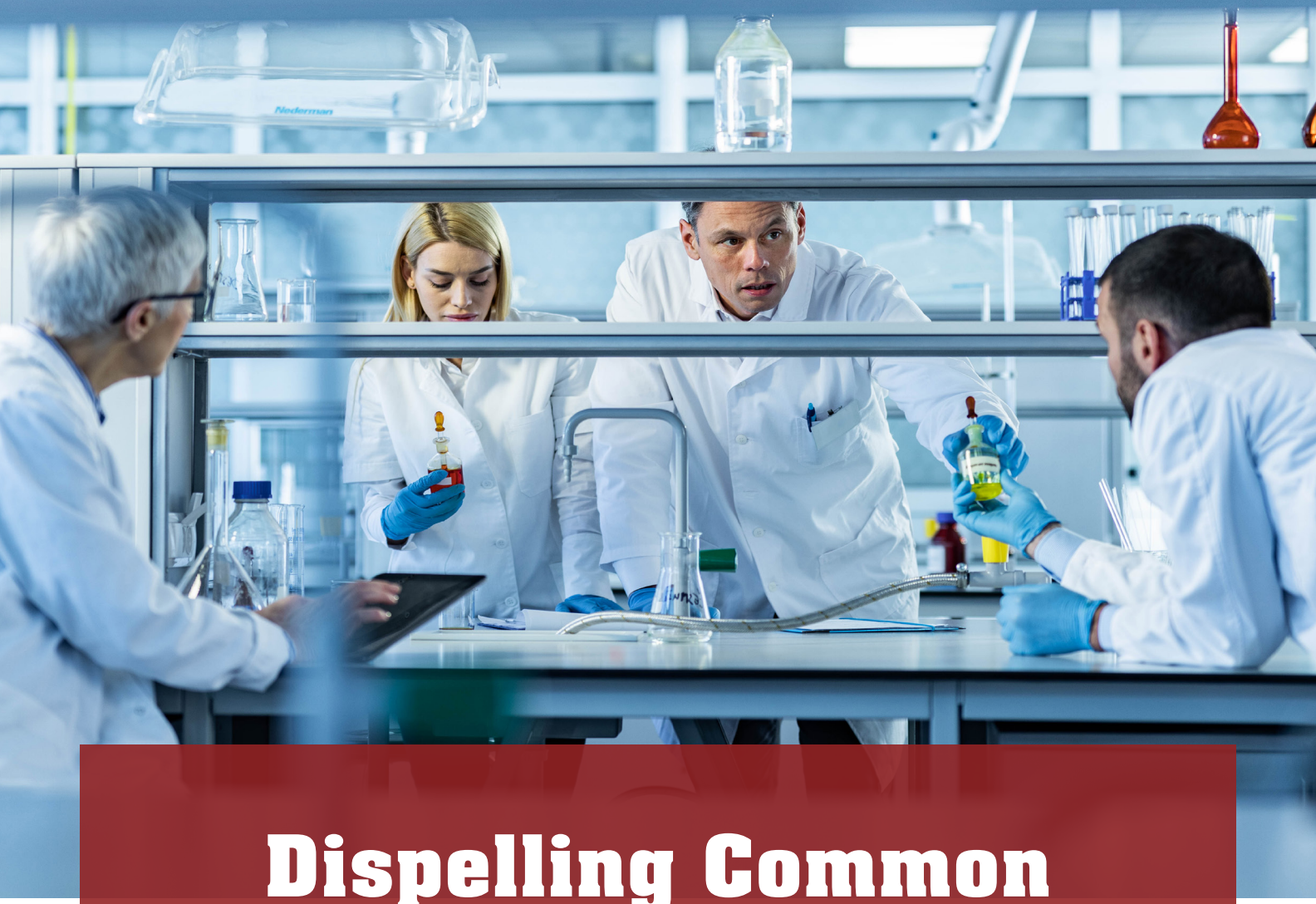
inSeption GROUP

Dispelling Common Clinical Trial Oversight Myths

Weak leadership and oversight beget confusion regarding accountability and responsibility for righting the ship, or even just keeping the ship on course.



Dispelling Common Clinical Trial Oversight Myths

Clinical trial leadership and oversight are the study sponsor's responsibility. No matter how well-regarded the outsourcing partner or how talented the team assigned to your trial, problems arise and mistakes are made. Weak leadership and oversight beget confusion regarding accountability and responsibility for righting the ship, or even just keeping the ship on course.

However, many oversight problems can be avoided or mitigated simply by the sponsor understanding what causes them and being a proactive collaborator with its partners. Addressing these four common pitfalls is a good place to start:

1. "We hired a big CRO, so they will take care of everything."

Misplaced faith in outsourcing partners impacts both large biotechs and small, early-stage, VC-backed companies. In short, when sponsor oversight is weaker than CRO management, a study can quickly become something unrecognizable to the sponsor. Misplaced faith in the CRO's oversight capability may be based on the sponsor's assumption that its science is sound and its product is exceptional, so a clinical trial will be simple and straightforward for a CRO to advance the project toward commercialization.

Accordingly, it can be challenging to explain to a financially oriented sponsor C-suite the importance of the sponsor's intimate involvement in the trial. Sponsors with relatively few employees rarely employ ClinOps personnel, and even larger companies may have limited ClinOps staff. But sponsor ClinOps defines key execution decisions during the conduct of the trial; they know how the project is supposed to be executed based on the protocol designed within the organization, and they have a more nuanced view of the science and development pathway.

Ensuring the CRO follows the intended road map may fall to a sponsor's senior ClinOps person, a chief medical officer, or a medical director, but it is imperative that a knowledgeable individual runs point on the sponsor side and acts as the face of the product to key opinion leaders (KOLs). Many challenges occur at a tactical level, requiring decisions that may not be fully outlined in the protocol or interactions between systems that could cause downstream difficulty. Delegating all responsibility to a CRO undermines the sponsor's visibility from a safety and medical perspective, leaving the sponsor ill-prepared to respond to their own needs or, in a worst-case scenario, missed endpoints.

2. "The more trials a CRO has run, the less the sponsor needs to be involved."

In this case, quality > quantity, because every clinical trial is custom-built. Just because an outsourcing partner has run a clinical trial before does not mean they ran it well. Critically, if the CRO ran a similar trial, will the individuals who drove success in that trial be assigned to your trial team?

The bigger the CRO, the more likely the answer is no, meaning the CRO's knowledge about your indication or your drug will not exist on your assigned team. This dynamic is exacerbated when developing novel drugs for which no similar trial or clear regulatory pathway exists. Those trials are bound to have twists and turns, which can be very difficult to manage when working under traditional fee-for-activity contracts.

Thus, focus specifically on the assigned team's quality. Inquire whether they have experience in areas you expect to be problematic, including their process for implementing expected changes informed by early-phase research. For example, a study working with a developmentally delayed patient population, spanning several neurological scales, needs a CRO project lead who can build an eCOA system to accommodate that specific scenario.

3. "A sponsor's internal team does not need trial expertise. It can rely on the CRO."

The sponsor's internal team is essential to trial success. That team determines outsourcing strategy and partners. Contracting a single CRO to handle most work while the sponsor team sits in the middle is a viable strategy but so is having a lab at one CRO and having eCOA handled by another — as long as the sponsor team retains direct insight into work and deliverables. In any case, the sponsor must always have high-level awareness of the trial. For this reason, the trial design and the strategy must be constructed around the program by the sponsor.

4. "A good outsourcing partner will follow directions and will not push back."

An outsourcing partner willing to challenge a sponsor is a desirable collaborator. It is vital, though, that the vendor's arguments are rooted in an understanding of the sponsor's goals and motivations. Accordingly, the sponsor and CRO ClinOps teams need to be experts in each other's organizations, so each can anticipate where issues may occur on the other side. Then, the teams can work together to develop cohesive solutions. A healthy partnership is someone plainly stating they think your idea or direction may be counterproductive to your stated goals and then helping you toward a solution.

Embracing Trial Ownership Drives Success

As the pitfalls of these four misconceptions show, clinical trial leadership belongs with the sponsor, and oversight is critical. For this reason, a knowledgeable internal ClinOps lead is essential to the success of any trial. Additionally, regardless of an outsourcing partner's organizational bona fides, a CRO ClinOps team with directly applicable experience is preferable to the team with the most overall experience. Informed vendor teams should feel empowered — and be encouraged — to ask tough questions, challenge the sponsor, and help find solutions. To learn more about clinical trial leadership and oversight, watch our recent webinar discussing the topic and visit https://inseptiongroup.com.

About inSeption Group

inSeption Group is a full-service, global outsourcing organization built on a foundational culture of exceptional service and quality. This culture attracts a subset of people who take a personal responsibility to deliver on what has been promised. inSeption Group's ability to custom-build teams with these experts, while providing valuable continuity, distinguishes our approach from traditional outsourcing options. In the changing landscape of clinical research, inSeption is building a new kind of future—one where transparency cultivates trust, integrity outweighs self-interest, and people deliver on their promises.