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CRO-Sponsor Partnerships

10 tips for enabling better CRO and sponsor collaborations

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The outsourcing of clinical research activities is anticipated to increase steadily to 72% by 2020, up from just 23% in 2012. When we think of outsourcing, we need to remind ourselves of the sponsor and contract research organization (CRO) goals. Sponsors are seeking the reduction of costs, access to specialized knowledge, and increased speed and agility. Meanwhile, CROs focus is on business goals related to economic outcomes for their owners, investors and shareholders. Each group is expecting deliverables and timelines to be met or exceeded for potentially different business reasons, leading to a traditional client/vendor-type relationship. Though alliances and partnerships are increasing between the two groups, there continues to be a client/vendor mentality at the operational and management levels which continue to perpetuate a lack of trust and empowerment.
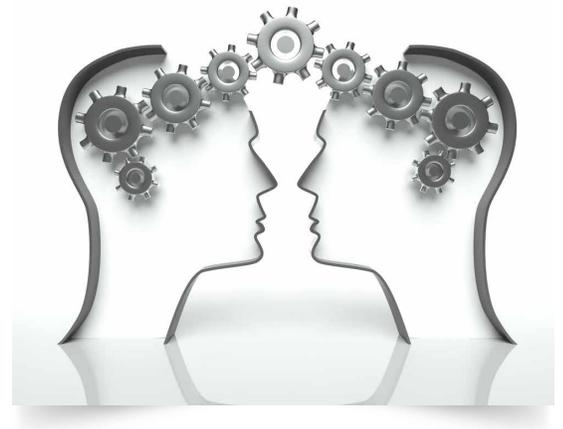
The reality is that the sponsor-CRO relationship is not always a win-win. While sponsors are clearly enticed by the efficiencies that can be gained through CRO use—a recent report from ISR projects that the CRO industry will grow at a rate of 7.4% CAGR through 2019—there is nonetheless a downside to the relationship. The fact is that a sponsor using a CRO must entrust the study performance to a third party, and that same performance is ultimately the measure upon which the sponsor's development organization is judged by its senior management. To date, sponsor and CRO interactions have been fraught with inefficiencies and needless duplication of task ownership. This lack of trust and inability to empower the partnerships leads to confusion and frustration for both parties.

In addition, the need for multiple partnerships for both the sponsor and CRO bring with it the complexity of different goals, processes, and culture. A sponsor's need for multiple partners to manage large pipelines, or the need for specific therapeutic experience, inevitably results in a complex operating environment with multiple moving parts. With differing business models and financial incentive goals the partnerships need a clear plan for success.

To a great extent, the future success of the life science industry in bringing new products to market rests on the ability of sponsors and CROs to work together successfully, providing both parties a compelling incentive to strengthen their partnership with the help of the right structure, tools, and strategies.

So what are some of the best practices to ensure a successful collaboration?

Ten tips for successful collaborations

1. Take the time to learn each other's "language" and culture with mutual due diligence. It is not just the responsibility of the CRO to learn the sponsor's processes, systems, and culture. For major collaborations, sponsor study teams need to invest in learning the ways of working at the CRO. Let's say you are outsourcing data management activities to a large CRO. It's worth talking about how that practice is done with other sponsors before you settle on approach. What can you learn about best practices, as well as, potential issues that might arise due to a required change in the routine process?

2. Establish a mutually agreed and practical communication plan with escalation parameters at all levels of the team including executive, management and operations. Collaborations often break down when communication breaks down. Make it a priority to create a practical communication plan with escalation procedures on both sides. What event(s) trigger an escalation? What information is generally expected to be communicated throughout the course of the study and by whom? Sitting down together and mapping out a robust communication and escalation plan is time well spent that will prevent fire-fighting in the future.

3. Develop and maintain a study/site risk assessment plan to ensure agreed risk mitigation actions in advance where possible. Performing on-going risk assessments at both the study and site level is a critical activity that drives quality of the data and ultimately successful study outcomes. The idea is to prevent problems before they become issues. The best way to do that is to identify the risks, design mitigations and interventions where possible, and communicate what you will accept as a risk as a study team.

4. Define business processes, including roles and responsibilities—these may go beyond the transfer of obligations agreement. Both the sponsor and the CRO have existing business processes and expectations for elements of the study life cycle. Whether you are talking about site initiation, data capture, data management, or monitoring, both sides have to adapt. Even if you defer to the sponsor business processes and systems, the roles and responsibilities will change. Make sure everyone on the team understands the overall process associated with key study activities and where they play a part.

5. Establish key performance indicators (KPIs) for partners and study deliverables. For outsourced trial activities, the disconnect between business model and management approach mentioned previously often has disastrous results. In many cases, sponsors find themselves managing by crisis, a situation in which individual vendors are only loosely managed until a crisis arises. One way to avoid surprises is to monitor quality and performance as you go by using KPIs. Make sure, however, that the KPIs are not created in isolation from the team—to be meaningful and effective, members must understand how the study progress is being measured and why.

6. Agree on the level of transparency and accessibility needed to ensure lagging KPIs and risk indicators are recognized in advance. It is not enough to monitor KPIs and risk indicators. What is the team going to do if there is a problem? Who is responsible and what communication channels

are used? This also relates to number 2 above.

7. Establish common team goals to be aligned with partner business goals where possible. Collaboration models range from fee-for-service to functional services to risk sharing on both sides. Regardless of where your model lies on the maturity curve, aligning team goals between partners is always a win-win.

8. Invest in software tools that enable communication, management, and automation of activities. Having a project plan, communication plan, KPIs, and risk management plan in place is not sufficient. Without the right tools to support communication, task automation, and transparency of information, all the hard work you do offline to set up governance and control will not be fully leveraged. Cloud-based platforms that enable immediate data sharing across partners are ideal for this purpose.

9. Develop incentives to motivate team members to support short-term study and long-term partnership expectations. This comes down to treating study team members as one, regardless of the organization. That means allowing CRO partners to have a say in things like protocol design, monitoring plan, and data management practices.

10. Create an atmosphere of positive collaboration. At its core, collaboration requires two-way communication and transparency. Creating an atmosphere of positive collaboration is important for the sanity of the team, and ultimately, the success of the study. This is not just a sentiment. Mechanisms should be put in place to enable two-way communication and feedback between CROs and sponsors. This is really about promoting a culture of continuous improvement.

Optimizing the partnership between sponsors and CROs is essential to realize the maximum value from the relationship. Inefficiencies inherent in sponsor/CRO interactions can be minimized by defining business processes, roles and responsibilities as well as communication plans, risk assessment plans and KPIs in the beginning of the collaboration. Getting the process right is only one aspect to consider; equally important is to implement the right tools to support process transparency, data sharing, and general collaboration across company lines.

These practices are the first step in the journey to move from a tactical client/vendor relationship to a more strategic operating model, where teams operate on a united front with shared goals and aligned structures and processes. This translates to increased resource productivity, cost savings, and ultimately, more successful studies.

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