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# Bringing Transparency and Collaboration to CRO Oversight

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**Relationships between sponsors and CROs are getting stronger** - The connection between sponsors and contract research organizations (CROs) is strengthening as outsourcing continues to be a clinical trial mainstay. Making the relationship between the sponsor and the CRO as productive as possible means acknowledging the ongoing transition away from tactical projects and toward strategic partnerships, with both stakeholders having a vested interest. This transition is taking many forms, but generally involves complexities, such as shared decision making, delivery of broad cross-study solutions, performance assessments, and shared risk and reward structures. At the core is a desire to build a collaborative long lasting partnership, which requires open and transparent communications, fostering a foundation of trust and commitment.

Research suggests that building relationships to improve clinical trial operations requires embracing centralized monitoring and study quality metrics as standard practice, and more recently, CRO oversight. Together, they form a solid basis for continuous quality management, but of these elements, CRO oversight has been gaining particular attention as sponsors sharpen their focus on how a clinical trial is progressing. One of the areas in need of greater CRO oversight is study startup (SSU), a perpetual bottleneck that continues to be handled largely by spreadsheets, shared file drives, and unsecured email, making data gathering and the timely sharing of data difficult in today's global market. As evidence that more SSU oversight is needed, it can take an estimated eight months to move from pre-visit through site initiation. For sponsors, improving oversight of this function means real-time visibility into study startup progress, affording greater confidence in the reports they receive from the CROs involved.

Because sponsors often have multiple studies running concurrently with multiple CROs, oversight is complicated, as each CRO has its own method for SSU and for transmitting information back to the sponsor. This can result in inconsistent and outdated data, making it difficult to benchmark the status of the various studies in the portfolio based on the performance of each CRO per therapeutic area and geographic area. By transitioning to a solution used by all CROs across the portfolio, oversight improves, and sponsors can build reliable institutional knowledge about CRO performance.

This article defines CRO oversight, describes the importance of relationship building, and takes a look at innovative solutions for streamlining SSU across CROs, a critical step toward reviewing study status in real-time.

## What is CRO Oversight?

As sponsors turn their attention to their core competencies, and continue to outsource, it is hardly surprising that stakeholders need a pathway to quality achievement as they build strategic relationships. Simply handing off multi-million dollar studies to CROs without carefully crafted plans for communications and reporting operational data as the study unfolds is hardly a wise move, yet what kind of oversight is needed, and how much is too much?

These are questions worth considering as reliance on CROs is on the upswing. A 2015 CRO outsourcing survey of 375 industry professionals showed that most respondents, 80%, anticipate growing demand for CRO services this year, particularly strategic services (60%) rather than tactical (40%). In addition, there is an expected 7.4% compound annual growth rate for the CRO market through 2019, and market penetration may reach a hefty 72% by the end of the decade 2020. This trend is rooted in intense competition to improve productivity, driving sponsors to contain operational and infrastructure costs while completing projects better, faster and more efficiently.

The issue of CRO oversight by sponsors is raised in the 2013 guidance put forth by the Food and Drug Administration (FDA) on risk-based monitoring. According to the guidance, if a sponsor delegates monitoring responsibility to a CRO, FDA regulations require the CRO to comply with them. Also, the sponsor retains responsibility for oversight of the work completed by the CRO(s) they select. The guidance spells out oversight as the sponsor's periodic review of monitoring reports and performance or quality metrics, as well as documented communication between the sponsor and CRO regarding monitoring progress. Importantly, both parties are to establish processes to exchange this relevant information.

Aligning with this guidance, sponsors see the size, scope, and complexity of clinical trials and their associated costs as justification for a degree of oversight that is well defined, transparent, and includes real-time reporting of study status and milestones. This approach addresses the problems inherent in gathering information from multiple CRO systems, causing lack of transparency, hard to see performance trends in SSU and other issues resulting from data compiled differently in each system. SSU oversight is complicated further by the fact that SSU is a process with numerous steps, namely country selection, pre-study visits, site selection and initiation, regulatory document submission, budget and contract negotiations, patient recruitment initiatives, and enrolling the first patient.

Considering that sponsors often work with several CROs, the challenge for overseeing these tasks is to find the right balance, rather than taking a heavy-handed approach whereby CROs feel they are being micromanaged. The goal is for the sponsor and CRO to operate as a team with shared risk, and agreed upon structures and processes. This is known as a centralized governance model, and entails gathering input from CROs so they are onboard with sponsor oversight, including the training needed for stakeholders to achieve the desired level of quality performance. Research indicates that sponsors and CROs want a clear understanding of expectations at the beginning of a relationship, and as they put together the centralized governance model, issues such as trust, commitment on both sides, good communication, openness and transparency and upfront planning need to be clearly defined.

The importance of building a good relationship between sponsors and CROs is featured in a 2014 survey of 127 sponsors and 105 providers (mostly CROs), conducted by The Avoca Group. The survey focused on the extent to which sponsors and providers, including CROs, are adopting intelligent, data-driven approaches to clinical trial execution. According to the survey, sponsors tended to be far more dissatisfied with the quality of work provided by CROs as compared to how CROs perceived their own work, but fortunately, there was an improvement in 2014 versus 2013. Specifically, sponsors (n = 88) reported being satisfied or very satisfied 59% of the time in 2014 versus 53% in 2013. By comparison, in 2014, providers (n = 71) were satisfied or very satisfied 96% of the time with the quality of the work they delivered to sponsors over the preceding 3 years, as compared to 87% in 2013.

There were other discrepancies in the survey between the perceptions of sponsors and CROs, but one of the more interesting ones relates directly to SSU activities. Respondents were asked whether sponsors engage CROs early in the process. Sixty-two percent (62%) of sponsors reported that they engage their CRO providers early in the clinical trial process always or most of the time, as opposed to 39% of providers making that claim for the same time period.

## CRO Oversight of the SSU Process

With research showing major differences in perceptions between sponsors and CROs regarding job performance, it is not surprising that these differences exist in several areas of clinical trial operations. SSU is one function widely recognized as needing improvement, given the number of sites required for global trials, the cost of initiating one site estimated at $20,000 to $30,000 , and another $1,500 per month per site for oversight. Better SSU starts with selecting CROs able to provide full visibility of study progress and milestones, which facilitates sponsor oversight. For SSU, cloud-based purpose-built technology that enables secured sharing of real-time data is gaining ground among CROs. Using an application program interface (API), the technology can integrate with other eClinical functions, such as electronic data capture, the clinical trial management system, and the electronic trial master file. This integration is pivotal for the various CROs participating in multiple studies as it optimizes flow of information among the various components. Moreover, the application acts as a single repository for in-progress documents, and information is accessed through a dashboard with a single logon, showing visualizations of study status across sites (Figure 1).

With this solution in place, sponsors can begin the process of CRO oversight (Figure 2), starting with configuring country workflows in accordance with the sponsor's quality standards. From this point forward, the CRO(s) can start selecting sites, and sending study-related documents, while keeping sponsors apprised of SSU status. There is real-time visibility into potential bottlenecks, allowing for prompt attention.

This cloud-based approach to oversight benefits sponsors and CROs alike. For sponsors, they can receive standard, consistent reporting across all CROs. They can also save CRO and site performance data for future reuse, and have full transparency at the portfolio, country, study, and site levels. Moreover, the rework and error rate would likely decline. CROs able to offer this type of efficiencies to sponsors would offer competitive advantage in a maturing CRO marketplace, and establish greater trust with the sponsor. In addition, the CRO would be able to reallocate resources to other value add tasks.

## The Value of Collaboration

Oversight of CROs by sponsors is here to stay, but in the spirit of collaboration, oversight is most effective as a partnership in which both parties benefit. The goal of the partnership is to enable greater transparency and visibility into trial data. The intelligence gathered from the data can improve SSU by helping clinical project managers identify bottlenecks, and take corrective action faster.

As clinical trials include sites from across the globe, cloud-based purpose-built solutions for SSU are playing an essential role in the oversight process by enabling CROs to tap into a single system for configuring workflows. With this information, the system provides visualizations whereby sponsors can see study status in real time. This is a significant improvement over the traditional method of each CRO using its own siloed approach to data gathering and transmission, especially if it relies on an array of spreadsheets and unsecured e-mails.

Finally, SSU solutions are offering significant change by putting CROs and sponsors on equal footing. Research bears out this notion, with both sponsors and CROs acknowledging that use of new technology can facilitate adoption of intelligent methods of clinical development. Going forward, this approach can help clinical trial stakeholders realize the full potential of outsourcing arrangements.

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