DRUG DISCOVERY & DEVELOPMENT

# Why FSP outsourcing of clinical operations roles is surging—and how to optimize your partnership

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As the complexity, sophistication, and size of clinical trials have grown exponentially, the need for specialized expertise—often spanning various regions around the globe—has also expanded, along with the demand for flexible staff allocation. Consequently, clinical operations staffing has undergone significant transformations in recent years.

The trend has shifted from relying on direct internal hires, to using contracting agencies and independent contractors to fill staffing gaps, to leveraging contract research organizations (CRO), often using full-service outsourcing (FSO) models. More recently, there has been a surge in demand for functional service provider (FSP) outsourcing of clinical operations functions driven by the need for sponsors to increase flexibility in resource allocation and access a quality global talent pool with a breadth and depth of needed expertise.

Decisions on whether to rely on internal hires or to outsource to staffing agencies or independent contract workers or to engage in partnerships with CROs must strike a strategic balance of expertise, cost, risk, flexibility, reliability and continuity. Ultimately, these factors all affect the sponsor's ability to invest in and expand their portfolios.

## The evolution of staffing clinical operations roles

As sponsors navigated through these evolving staffing strategies for clinical operations, it became evident that each approach offered distinct advantages and challenges, paving the way for the development and adoption of more flexible and efficient models to meet the demands of modern clinical trials.

Historically, sponsors relied primarily on direct hires for clinical operations roles. The direct hires option continues to offer sponsors the most control and stability, but it is also the least flexible choice. A large allocation of internal staff can be a constraint in the face of fluctuating work volumes. Sponsors also often struggle to find and hire the right expertise, especially for specialty roles and/or in geographies where they have limited or no operational footprint.

Using some independent contractors—either independently or through contracting agencies—became another popular option, but sponsors often found that contract workers are better suited to short-term or part-time requirements and can increase co-employment and misclassification risks.

The rise of CROs precipitated a seismic shift in how clinical trials get done. Historically, CROs were most typically engaged using FSO models, which offer end-to-end clinical development services across a trial. FSP approaches, which involve outsourcing some or all of one or more functions to a CRO, potentially across the entire portfolio, are now gaining favor as they allow the sponsor to more closely maintain control over project delivery and costs and offer more flexibility.

Employing an FSP model isn't a one-size-fits-all solution. FSP engagements can flex to complement a sponsor's existing capabilities with dedicated functional expertise in targeted areas. An FSP partner, for example, could deliver an end-to-end clinical operations solution that encompasses all needed expertise, services, technologies and processes. It could also incorporate a blend of sponsor, CRO and vendor tools, technologies and processes. The strength of the FSP model is that it allows the sponsor to tap needed expertise while delivering the flexibility to meet the specific needs of each sponsor and situation, including the ability to ramp up or down to accommodate fluctuating workloads.

As the FSP model is becoming more broadly acknowledged for meeting the needs of the moment, the result has been substantial growth. In a recent survey, over 41% of respondents reported greater use of FSP models compared to the FSO model's 29% growth.1 The survey also found that a mix of hybrid FSP/ FSO models has also become popular with FSP or hybrid FSP/FSO arrangements being used by 87% of drug developers.

Choosing the right FSP partner is critical for successful outsourcing of the clinical operations functions. Here are four key questions to ask a potential FSP partner to drive on-time and on-budget trials.

### 1. How do you ensure the quality of your staff?

The caliber and commitment of the clinical research associates (CRAs), clinical trial coordinators (CTCs), and other clinical operations staff has a profound impact on the success of a clinical trial. These are the staff on the front lines; their monitoring and trial oversight procedures are essential for avoiding protocol deviations, poor data quality, and regulatory issues to protect patient safety, avoid trial delays, and other serious consequences.

The quality of clinical operations staff is often what differentiates top-tier providers. In FSP partnerships, these critical experts are often involved throughout the lifecycle of the study from qualification to close out—making their selection, training and cross-training, and continuity critical. In a hypercompetitive clinical operations talent market, it's especially important to consider the steps your FSP partner takes to hire and develop top-tier staff. As one example, PPD FSP solutions offers CRA Academy, a training program for highly motivated entry-level CRAs that transforms them into highly qualified CRAs. The CRA Academy combines soft skill development, therapeutic e-learning, technology training, instructor-led scenario-based sections, and role playing to prepare CRAs for the challenging situations they may face on site.

Staff retention rates are another critical data point to evaluate as the continuity of your clinical operations team can have profound quality implications. For example, each time a new CRA visits an investigative site, the data must be handed off and the new CRA must be trained about the sponsor and their processes, the trial, and the patient journey. The relationship between the site and CRA also starts from scratch.

Structuring FSP engagements as long-term partnerships also helps maintain high staff quality as this arrangement allows clinical operations staff to work within a client's systems and build deep sustained relationships with site staff that can help avoid disruptions, uphold high-quality data collection, and optimize efficiency.

Moreover, as the role of the CRA continues to evolve, engendering new types of roles like 'site relationship leads' and 'site engagement leads,' that create a single point of contact between the site and the sponsor to strengthen the relationship, reduce site burden, and continuously promote quality. The simple fact is that sites are more willing to engage in trials when they work with high quality staff who bring a deep knowledge of the sponsor's product and way of working. When an urgent problem arises on site, site staff need quick answers and support.

Above and beyond the site-facing staff, it is important to have FSP clinical operations management roles overseeing quality across teams—including global teams. This transfers pressure from the sponsor to the FSP who maintains accountability for ensuring quality and study delivery at the site level.

### 2. Does the FSP partner have the global footprint to optimize the trial?

As clinical trials grow to include more diverse participants across more parts of the globe, developers find advantages in FSP partnerships with well-established global operations that combine centralized resources with FSP resources that bring in-country local expertise on a wide variety of fronts—from regulations to clinical processes, to languages and cultural differences. For example, PPD FSP solutions has resource hubs in four regions—Latin America, India, China, and Central and Eastern Europe—each with local teams who know the local culture and regulations and are supported by a broad range of centralized professionals and services to meet a wide range of needs in a variety of applications.

For example, sponsors may embed local FSP managers at the country level as part of their own extended team, overseeing local team training, interacting with the project leadership team, and generally driving delivery across their workforce to help ensure that operations are in line with key performance indicator (KPI) targets.

A de-risking strategy that's increasingly used by sponsors to address intense competition for patients at sites is the expansion of clinical research into "non-footprint" countries, often in emerging markets or remote areas, where the drug developer lacks a legal entity. Expanding to regions with untapped patient populations and research sites with lower clinical trial activity helps deliver more consistent enrollment and heightened staff engagement.

Expanding into non-footprint countries, however, poses considerable challenges for sponsors that FSP engagements can mitigate. For example, deploying CRAs from footprint countries into non-footprint countries would introduce challenging language and cultural differences. Well-established global FSP partners, on the other hand, have local professionals that speak the native language, know local regulations and customs, and have existing relationships with sites, vendors, and trusted key opinion leaders — all critical factors to speed patient participation rates and protect the integrity of the trial.

Another global approach gaining favor and better enabled by FSP engagements are follow-the-sun (FTS) models. These creative solutions can create around-the-clock productivity by using global teams of FSP resources strategically located across different time zones. Work can seamlessly be transitioned—either between split-shift functional teams handing off tasks at the end of the day or cross-functional teams handing off data—ensuring a continuous flow of work to meet timeline and budget commitments. It can also avail experts at any time, no matter the home country or time zone.

In addition, employing a global FSP workforce can leverage resources in more cost-efficient regions. For example, in countries where remote and cross-border monitoring is allowed, a sponsor can centralize its processing and analysis at whichever location best suits the budget and goals. The key is consistent staff training that emphasizes critical thinking, focusing on risk assessment, data analysis, and problem-solving.

### 3. How does the FSP partner leverage risk-based methodologies, data analysis, and technology innovations to drive quality and mitigate risks?

To avoid issues, setbacks and delays, ideal clinical operations approaches are rooted in the understanding that it is difficult to fix a problem once it has occurred, and the focus should be preventative versus reactive. The clinical operations staff provided by your FSP partner should be trained in risk-based quality management (RBQM) to apply risk-based approaches, root cause analysis, critical thinking, and problem-solving skills to proactively identify specific issues and focus on expedited resolution to mitigate the risk for business disruption.

In many cases, risk-based processes can be foundational. For example, in monitoring, whereas the traditional methods of source data verification and source document review focus on past events, risk-based monitoring (RBM) shifts the focus towards the present and future, emphasizing real-time monitoring and predictive modeling. It also takes advantage of ongoing advancements in technology, risk-based approaches, and data analysis to use resources strategically and efficiently in proportion to risk.

Other recent rapid advances—during and after the COVID pandemic—have proven their value and catapulted adoption, including sophisticated digital capabilities, decentralized approaches, new technologies, tools and methods, and data analysis on numerous fronts.

A hallmark of FSP arrangements is that they tend to be longer term partnerships with stable teams in place—either across a single function or multiple functions in a clinical trial or in a portfolio of trials—to develop RBQM systems and processes to implement innovative technologies or approaches, apply them consistently, gather feedback, and make incremental improvements.

### 4. Can the FSP partner help increase patient diversity?

Clinical operations is rapidly evolving the meet the challenges of locating, enrolling, and supporting ever-more culturally and geographically diverse patients. Your FSP partner should be well positioned to facilitate access to the patient population targeted by the trial. This may include making early recommendations for protocol optimization, developing highly targeted patient engagement plans, implementing decentralized elements and patient monitoring and analysis capabilities that extend clinical trials to a broader range of patients, and providing culturally sensitive site and patient educational materials that are built on real-life insights about patients.

### Conclusion

The increasing demand for FSP outsourcing for clinical operations reflects the complexities faced by sponsors as pressure mounts to efficiently deliver larger trials on tighter timelines. The shift towards FSP models allows sponsors to enhance flexibility in resource allocation, access specialized global expertise, and put stable teams in place to deploy innovative new approaches. To ensure success, sponsors must engage FSP partners who prioritize the quality of staff, possess global reach with local resources, have expertise in new technologies, risk-based methodologies, and diverse patient population engagement. FSP strategic partnerships empower sponsors to navigate ever-evolving challenges with confidence and continue advancing patient-centric research while adhering to patient safety, regulatory compliance, and study timelines. **DD&D**