

FSP Resource Efficiencies: Resolving Challenges While Optimizing Outcomes

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Functional service provider (FSP) models have provided alternatives to the full-service clinical development outsourcing approach for more than 25 years. Typically, they were seen to support a company's need to augment and expand its workforce for a particular function.

FSP models have been used with different service areas such as monitoring, biometrics, and safety, typically being an outsourcing approach embraced only by larger sponsor companies. But as research and development spending has continued to grow over the past few decades, clinical research has evolved. FSP organizations have evolved as well; they're no longer just about staff augmentation.

There are numerous approaches and models that can be deployed to meet the specific needs of a sponsor. They include CRO- and client-managed models—or a hybrid of both—that are supported by several financial constructs, such as unitized or timing materials, monthly or yearly full-time employees, and even as milestone models.

Often hybrid models are used to drive optimal efficiencies based on specific needs. Industry trends illustrate that large and mid-sized companies are decreasing their dependencies on full-service offerings (FSO) in favor of FSP firms. And there is a trend and shift across biotech companies in general.

The need for flexibility, expertise, and alternative solutions makes FSP solutions more viable now than ever.

Q: What do you see currently in the industry that prevents or challenges companies from embracing the FSP model?

One of the main challenges is that an organization transitioning from internal operations or a full-service model may struggle to fully understand the FSP approach and ensure appropriate oversight. It is common to see companies apply excessive oversight to the FSP organization. This can be easily avoided by creating a RACI matrix with clearly defined responsibilities and accountabilities, and by establishing a governance structure.

Excessive oversight of the FSP resources can lead to increased costs, which may prevent the client from realizing the financial benefits of the FSP program. The management of the FSP program itself can become a significant expense, so it is essential for the client to manage it carefully.

Q: How will the industry evolve over the next several years when it comes to FSP resourcing and models?

As an industry, continued focus on outcomes remains essential. Success is ultimately tied to the success of the drug. Within the FSO model, incentive alignment can sometimes be lacking, particularly between smaller organizations and their providers. Smaller organizations will likely continue to rely on outsourcing to larger entities to achieve scalability, reach, and access to regions and functions they may not wish to build internally.

The industry would benefit from increased transparency between the outsourcing organization and the service provider. When specific challenges arise in a trial or organization, it is important that both parties collaborate as one team to develop aligned solutions, rather than working independently toward separate answers. By bringing together expertise from both organizations, more effective solutions can be developed. The FSP model supports this collaborative approach.

Technology plays a critical role in enhancing transparency. Within FSP programs, the ability to manage resources dynamically is key. As workload increases, resource levels can be scaled up; as it

decreases, they can be scaled down. Contracts typically include language around the timing for scaling. By leveraging technology—such as a resourcing system where the client inputs study information and resource needs projected months in advance—a resource plan can be built. If the FSP provider has access to the same plan, it enables proactive scaling rather than reactive, just-in-time adjustments. This leads to improved staffing, reduced turnover, and fewer conflicts between the two organizations.

Another advantage of embracing technology is improved access to data. Operational and clinical trial data often reside in disparate systems, making access cumbersome. Timely access to unified data sources enables better decision-making. The Worldwide Flex approach, which includes developing solutions linked to technology, processes, and people, exemplifies this. It's about adjusting various levers to optimize outcomes.

Looking ahead, the goal is to foster partnerships that leverage mutual strengths and integrate experiences across organizations to accelerate timelines and reduce costs. Achieving this will require a shift in mindset toward more collaborative research practices.

Q: What do you see as the benefits of an FSP model that leverages a global workforce?

The talent available from countries across the globe is exceptional. Key benefits include coverage across multiple time zones, more diverse teams, and improved access to specialized skills.

Restricting recruitment to a single location can create significant challenges—not only in terms of skill sets but also in volume. For example, if there is a need to rapidly scale up a function by 100 to 200 people, limiting the search to one location with specific skill

requirements can be like searching for a needle in a haystack. Expanding the search globally offers far greater opportunities.

If time zones are managed effectively—a common concern—work can progress continuously throughout the day with appropriate handovers for suitable roles. This requires thoughtful planning, tracking, and communication.

There are many tools that effectively address concerns related to time zone differences. The client must plan for this and foster collaboration.

Although COVID-19 was a challenging period, it led to a shift in work practices. Virtual collaboration has become the norm, even within the same country or organization.

This shift supports the feasibility of global teamwork.

Success depends on purposeful engagement and clear communication, recognizing that colleagues may no longer be physically nearby. This is the new way of working. Leveraging a global workforce presents a strong opportunity for achieving optimal outcomes.

Q: Why would an organization, such as a small biotech, benefit from using an FSP model?

A key consideration is identifying which resources must be retained internally. For example, business unit leads and department heads may need to remain as permanent staff to establish infrastructure and drive the business model, while also holding certain financial responsibilities within the organization. The FSP model can then be used to support workflow in a flexible manner, allowing the client to scale resources up or down as business needs evolve.

This approach helps avoid unnecessary costs and enables rapid onboarding and offboarding.

The model provides flexibility to manage the workforce in alignment with workflow demands. It also allows the client to bring in individuals with specific expertise required for a particular trial or region, especially in cases where building a permanent team is not desired or feasible.

Craig McIlhone brings 25 years of experience in drug development with small and large CROs to his role with Catalyst. As President of Worldwide Flex, Craig is responsible for the global execution of functional services across multiple therapeutic areas. In his previous roles Craig has overseen global operations across multiple functions including but not limited to data management, biostatistics, statistical programming, medical writing, quality, analytics, systems and communications. He earned a B.S. (Hons) degree in statistics from the University of Glasgow, U.K. and an M.S. in applied statistics from Napier University, Edinburgh, U.K. He is a chartered statistician (Cstat) with the Royal Statistical Society and was previously a director of the Statisticians in the Pharmaceutical Industry (PSI).