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Modernizing Clinical Trials

The Strategic Shift Toward Functional Service Provider Models

WRITTEN BY:

Benjamin P Stephenson, MBA
Emmanuelle Hoarau, PhD

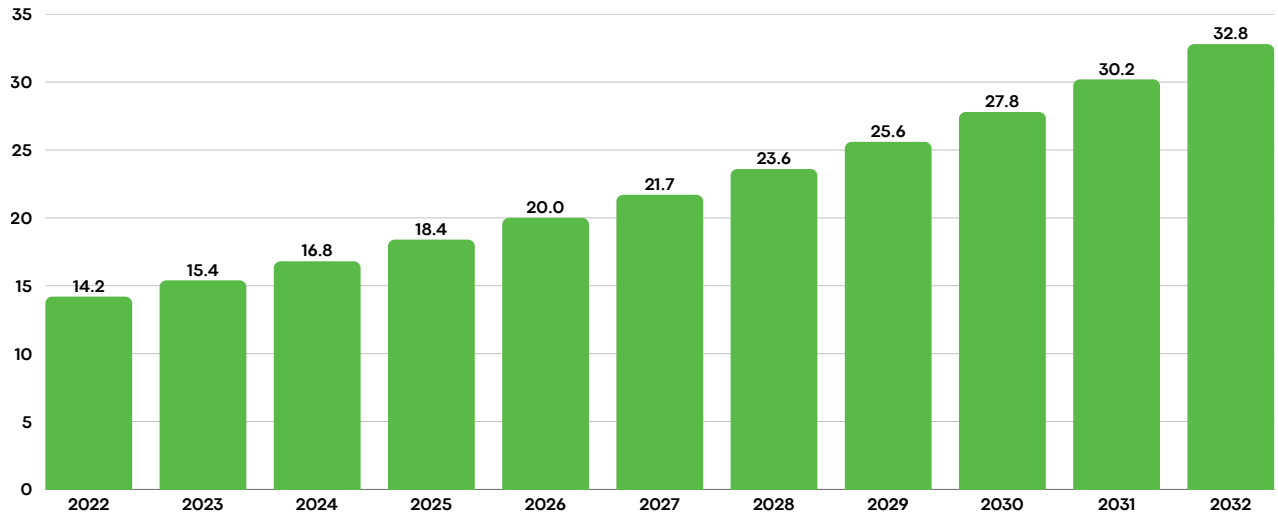
Purpose Statement

The landscape of clinical research is undergoing a significant transformation, shaped by the increasing complexities of drug development and the urgent need for operational efficiency. Traditional models of clinical trial management, which heavily relied on in-house resources and contract research organizations (CROs), are being challenged by more innovative approaches that address the multifaceted nature of clinical trials. Among these, the Functional Service Provider (FSP) model has emerged as a superior alternative, offering enhanced flexibility, cost-effectiveness, and access to specialized talent for pharmaceutical, biotechnology, and medical device organizations. The Purpose of this paper explores the comprehensive benefits of the FSP model, emphasizing its impact on talent acquisition and operational efficiencies, as well as its strategic alignment with the unique needs of clinical development in today's fast-paced environment.

Introduction

As the pharmaceutical and biotechnology industries strive to bring novel therapies to market, they face numerous challenges, including rising costs, stringent regulatory requirements, and a competitive landscape that demands quicker time-to-market. According to industry estimates, the average cost to develop a new drug now exceeds $2.3 billion[1], and the timeline can extend over a decade. This financial burden has compelled organizations to seek more efficient and innovative solutions, particularly in the realm of clinical trial management. The FSP market itself is a testament to this shift, with a valuation of approximately $18.4 billion in 2025 and a projected growth to over $30 billion by 2032, expanding at a robust compound annual growth rate (CAGR) of about 8.6%.[4] Traditional staffing models, often inflexible and slow to adapt, frequently lead to operational inefficiencies and delayed project timelines. In contrast, the FSP model allows organizations to retain control of their clinical operations while embedding workers into specific functions or services, providing a tailored approach to meet client needs. This flexibility is especially crucial in an era where agility and rapid responses to market dynamics can significantly influence a company's success.

FSP Market Value Growth (USD Billions)



Source: coherentmarketinsights.com

Background on the FSP Model

The FSP model provides a distinct framework for outsourcing that focuses on specific functions within clinical trials rather than the entire project. This approach fosters collaboration between sponsors and service providers, enabling organizations to leverage specialized expertise while maintaining critical oversight and strategic control of their operations and data. This retention of control is a fundamental differentiator from Full-Service Outsourcing (FSO), where entire trials are delegated, often limiting a sponsor's direct influence. As the demand for niche clinical expertise grows, FSPs have become vital partners for companies aiming to optimize their clinical development processes. FSPs are particularly effective in addressing gaps in internal capabilities, allowing organizations to quickly fill specialized roles that may not be justifiable to maintain in-house on a long-term basis. This model also mitigates the risks associated with talent shortages and fluctuating workloads, providing a scalable solution that can adapt to the ebb and flow of clinical trial demands. By aligning resources with specific project requirements, FSPs can offer tailored support—ranging from talent augmentation and managed workforces to tech-enabled solutions—that enhances the efficiency of clinical operations.

The adoption of the FSP model is widespread, but the primary drivers differ significantly between large pharmaceutical companies and their small-to-mid-sized (SMB) counterparts. For Large Pharma, the core motivation is achieving operational efficiency and cost optimization across vast, global portfolios. These organizations leverage FSP to manage high-volume, repeatable functions like clinical monitoring and statistical programming, freeing internal resources to concentrate on core R&D activities.[1] This strategy is proving effective, with FSP usage by large biopharma growing at over 13% annually.[9] (Case Study: Improving performance through Training & Process Optimization)

In contrast, SMB biotech and biopharma companies turn to FSP primarily to access critical capabilities and enable rapid growth.[10] (Case study: "Success in placing clinical scientists in the biopharmaceutical industry"). Often operating with lean teams, they use FSP to gain immediate access to specialized talent in areas like regulatory affairs or biostatistics, which would be too costly to hire permanently, allowing them to scale operations for pivotal trials while maintaining tight control over their core assets and budgets.[10] Geographically, the FSP market is dominated by two key regions: North America and Europe. North America currently stands as the largest market, commanding over 45% of the global share, driven overwhelmingly by the high volume of clinical trial activity in the United States.[5] The region hosts a mature ecosystem of major pharmaceutical companies, a vibrant biotech sector in hubs like Boston and San Francisco, and the headquarters of premier FSP providers, creating sustained demand for services in clinical operations, biostatistics, and FDA-focused regulatory affairs.[10]

The European market ranks as the second largest globally for Functional Service Provider (FSP) solutions, driven by its emphasis on regulatory compliance, patient safety, and a robust pharmaceutical industry that continues to fuel demand for FSP.[5] This explosive growth is fueled by Nations such as Germany, the United Kingdom, and France who play a major role in advancing clinical research through substantial investments and the use of innovative trial methodologies. Europe's growing emphasis on patient-centered strategies and the adoption of digital technologies further strengthen its position as a leading market in the global clinical research landscape.[5]

The demand for FSP services spans several key departments within sponsor organizations, each with distinct talent requirements. The Clinical Operations and Clinical Development departments are the largest users, primarily seeking talent to execute trials. This includes highly skilled Clinical Research Associates (CRAs) responsible for site monitoring, Clinical Trial Coordinators (CTCs) who manage administrative tasks, and Site Engagement Leads focused on optimizing site relationships.[13]

Simultaneously, Regulatory Affairs and Quality Assurance departments leverage FSP for specialized expertise in navigating complex global regulations. The talent delivered includes senior Regulatory Affairs Leads who provide strategic guidance, technical specialists with expertise in areas like Chemistry, Manufacturing, and Controls (CMC), and publishing experts who ensure technically flawless electronic submissions. Finally, the Biometrics and Data Management departments rely on FSP to ensure the analytical integrity of their trials. This involves embedding expert Biostatisticians, often holding advanced degrees, to consult on study design, alongside Statistical Programmers who create the compliant, submission-ready datasets (SDTM/ADaM) and analyses required by health authorities.

Benefits of the FSP Model

Access to Specialized Talent

FSP partners provide direct access to pre-vetted, functionally aligned talent with deep therapeutic and regulatory expertise. As clinical complexity grows, the ability to engage experienced resources on-demand, such as biostatisticians with experience in adaptive trial design or regulatory experts in orphan drugs, allows sponsors to remain nimble and competitive.[16] According to Getz et al. (2022), one of the key advantages of FSP lies in rapid talent deployment and enhanced retention compared to traditional staffing or transactional CRO engagements. FSP providers typically invest in ongoing training and development, ensuring their professionals remain up to date with evolving regulations and technologies. This commitment to talent excellence enables sponsors to benefit from workforce continuity, reducing disruptions and ramp-up time across projects. Leading FSP providers actively combat the industry's high talent turnover by fostering stability; for instance, some report FSP staff turnover rates as low as 12%, significantly below the industry averages.

Cost-Effectiveness

A key benefit of the FSP model is its cost efficiency. Sponsors only pay for specific functional roles or services, reducing overhead and converting the high fixed costs associated with full-time employees into manageable variable costs. This article by Shah[3] points out that the shift to FSP/hybrid models from 2024–2025 was driven in large part by favorable economics and better return on investment. Industry analyses consistently show that FSP models can generate cost savings of 15% to 30% compared to FSO or in-house approaches. (Case study: Optimizing Medical Writing for a global medical device company). Unlike FSO contracts that often require upfront resource commitments, FSPs provide elastic engagement models that scale with project demands. This financial agility allows sponsors to focus investments on innovation and core R&D activities rather than operational infrastructure.

"FSP Models Can Generate 15%-30% Cost Savings Vs. FSO or In-House Approaches"

Enhanced Operational Efficiency

By embedding specialized resources, FSPs enable faster decision-making, fewer handoffs, and tighter oversight of timelines and KPIs.[10] Operational ownership remains with the sponsor, which leads to better governance and fewer surprises during execution. Getz et al. (2022) highlight that the industry is moving toward a more granular classification of outsourcing models—emphasizing the need for shared accountability and process alignment that the FSP model naturally supports. Furthermore, FSPs often leverage advanced systems integration and dashboards, providing real-time visibility into operational metrics through technologies like AI, machine learning, and risk-based quality management (RBQM) platforms. This transparency supports early risk detection, proactive mitigation, and smoother cross-functional coordination across global trial portfolios.

Challenges & Considerations of the FSP Model

Despite its clear advantages, the FSP model is not without its challenges and requires careful management to be successful. A primary struggle is the increased governance complexity and oversight burden placed on the sponsor. Unlike an FSO model where management is largely delegated, FSP requires the sponsor to invest significant resources in vendor relationship management, performance tracking, and ensuring seamless integration between external and internal teams. This can lead to the creation of functional silos if not managed properly, resulting in misalignments, inefficiencies, and finger-pointing between teams. Furthermore, from a human resources perspective, FSP roles can present challenges for the outsourced professionals, who may feel caught between the two cultures of the CRO and the sponsor, sometimes facing a perceived ceiling on career progression which can impact morale and retention. Successfully navigating these struggles requires robust strategic planning, strong governance structures, and clear, continuous communication to ensure all parties are aligned on objectives and processes.

Comparative Advantages of the FSP Model

The table Comparative Analysis: Why FSP Outperforms FSO & Staffing highlights the distinct advantages of the Functional Service Provider (FSP) model over traditional staffing and Full-Service Outsourcing (FSO) models in the context of clinical trials. It emphasizes that FSP models provide greater strategic oversight, as sponsors retain control over their operations, unlike FSO models where the majority of operations are managed by the CRO, as shown in Figure 1. Additionally, the FSP model offers high-cost transparency, allowing for predictable full-time equivalent (FTE) rates, in contrast to the less transparent, often variable pricing structures seen in staffing and FSO models. The table also underscores the continuity of talent in the FSP model, with dedicated, long-term teams, compared to the high turnover seen in staffing or the varying talent stability in FSO models.

Furthermore, while the FSP model boasts global scalability, allowing providers to deploy resources across regions effectively, staffing is often limited to regional talent pools, and FSO models leverage the broad reach of CROs.[10] Finally, when it comes to compliance and risk, the FSP model ensures that these factors are managed within the sponsor's systems, reducing risk exposure, whereas in FSO models, these responsibilities are often delegated to the CRO, which can lead to variable outcomes depending on the CRO's practices.[10] Together, these factors position the FSP model as a superior solution for companies aiming to optimize their clinical development processes, mitigate risks, and improve operational efficiency.

FSP/FSO/Staffing Comparison

Feature	FSP Model	FSO Model	Traditional Stafing
Strategic Oversight	High; Sponsor retains control over operations and data.	Low; CRO manages most operations and decision-making.	High; Direct management of internal or contract staff.
Cost Transparency	High; Predictable FTE or unit-based rates with no change orders.	Moderate to Low; Milestone-based pricing with potential for costly change orders.	Variable; Dependent on individual contractor rates or internal salary costs.
Talent Continuity	High; Dedicated, long-term teams with lower turnover rates.	Variable; Resources may be split across multiple clients, leading to higher turnover.	Low; Often used for short-term needs, leading to high turnover.
Scalability	High; Resources can be scaled globally and rapidly based on project needs.	Moderate; Scaling can be rigid and may require contract renegotiation.	Low; Limited to regional talent pools and individual availability.
Compliance & Risk	Low Risk; Managed within sponsor's systems and SOPs, ensuring alignment.	Variable Risk; Dependent on CRO's systems and quality standards.	High Risk; Co-employment and misclassification risks can be significant.

Figure 1

Regulatory Compliance & Quality Assurance

FSP resources often bring domain-specific regulatory knowledge and the flexibility to rapidly adapt to shifting global requirements. In a recent case, a large medical device manufacturer partnered with Kelly's Functional Service Provider (FSP) model to overcome urgent regulatory compliance challenges caused by evolving legislation in the EMEA and APAC regions. (Case study: Accessing Scarce Regulatory Affairs Talent With Our FSP Model). The client benefited from timely access to over 25 skilled regulatory affairs professionals within three months—ultimately scaling to more than 60 experts across 19 countries. This strategic deployment ensured adherence to complex international regulatory frameworks, such as the EU's Clinical Trial Regulation (CTR) and In Vitro Diagnostic Regulation (IVDR). The FSP model's comprehensive training, mentoring, and talent management support contributed to improved compliance and significantly reduced turnover. These initiatives resulted in a 14% cost savings through better budget control, while fostering a stable and well-supported regulatory workforce. Importantly, embedded FSP quality systems helped standardize compliance practices and ensure consistent alignment with sponsor SOPs, reducing variability across regions. This case illustrates how a well-executed FSP model not only ensures regulatory readiness but also enhances long-term compliance maturity and organizational resilience.

Global Reach & Diversity

FSP providers operate across geographies, enabling sponsors to expand into new regions and "non-footprint" countries without building permanent local teams.[14] This is especially valuable for enrolling diverse patient populations and managing country-specific requirements. Getz et al. (2022) note that FSP models allow for tailored, scalable resourcing approaches that support both global trial expansion and regional sensitivity. With increasing regulatory emphasis on diversity, FSPs are well-positioned to support enrollment strategies that reflect real-world patient populations. Their ability to tap into local expertise, languages, and community partnerships accelerates startup and strengthens participant engagement, whether navigating the complex, multi-country environment of EMEA or leveraging the large, treatment-naïve patient populations of the APAC region.[9]

About The Authors

Benjamin P. Stephenson, MBA

Benjamin P. Stephenson is a senior executive with nearly two decades of experience leading global clinical operations and workforce strategy in the pharmaceutical, biotech, and medical device industries. As Senior Vice President of Global FSP Operations and Strategy at Vita Global Sciences, he partners with top-tier life sciences organizations to design and implement scalable, compliant FSP models that support clinical, regulatory, and medical functions across 35+ countries.

With deep expertise in aligning operational delivery to R&D objectives, Benjamin enables sponsors to optimize resource deployment, accelerate study timelines, and enhance continuity through tailored functional resourcing strategies. He leads diverse teams of program managers, talent acquisition experts, and engagement specialists who deliver consistent execution, measurable results, and exceptional client service.

Previously, Benjamin held senior leadership roles at Kelly Services, where he helped shape and expand global FSP capabilities supporting leading pharma and device clients. He is also a former Executive Steering Council member of the Association of Clinical Research Professionals (ACRP), where he advanced initiatives focused on increasing diversity and inclusion in clinical trials and the research workforce.

Benjamin holds a bachelor's degree in Human Biology and Health Care Administration from the University of Michigan and an MBA in Strategic Leadership. He is certified in cGMPs, LEAP (Lead, Engage, Advance, Perform), and InsideOut Coaching. His leadership has earned industry honors including the SET Legends Circle Award and Kelly Honors Finalist for "Winning Through Our People."

Emmanuelle Hoarau, PhD

With a PhD and deep domain expertise, Emmanuelle Hoarau serves as Domain Intelligence Director at Kelly Science & Clinical, based in the Paris region. In this leadership role, she oversees market insights and strategic talent intelligence across life sciences, bridging science, engineering, and medical device sectors to deliver impactful hiring and workforce solutions.

She leads a team focused on identifying industry trends and connecting top scientific talent with organizations at the forefront of biotech, pharmaceuticals, and biomanufacturing. Her data-driven approach helps clients build teams aligned with current and emerging needs in research and operations.

A recognized thought leader, Emmanuelle frequently shares insights on drug discovery, biomanufacturing, and medical devices through LinkedIn and webinars, with a focus on topics like AI in drug development and life sciences talent trends. She has built a strong professional following, known for her expertise and engagement in domain intelligence.

Emmanuelle's leadership combines analytical rigor, industry insight, and a passion for advancing scientific excellence within her clients' organizations.

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