ThermoFisher SCIENTIFIC

Thought leadership

FSP trends report

A guide for biopharma and biotechnology organizations to maximize their FSP engagements–and capitalize on the latest trends–to achieve on-time, on-budget project delivery from their FSP partners.

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Executive Summary

As the clinical research landscape intensifies and trials increase in complexity, drug developers face growing pressure to deliver on-time, on-budget studies that accelerate therapeutic development. The 2024 FSP Trends Report from the PPD™ clinical research business of Thermo Fisher Scientific explores the growing utilization of functional service provider (FSP) arrangements to manage the intricacies and challenges of the pharmaceutical industry. FSP arrangements have emerged as a pivotal strategy for biotech and biopharma companies to access complementary expertise and resource flexibility to meet their timelines, and innovative providers are implementing new, globalized FSP strategies to keep their clients ahead of the curve.

This report explores:

- The latest utilization and growth projection of FSPs in clinical research,
- The future of FSP strategies and models, and
- The keys to successfully leveraging an FSP model to drive on-time, on-budget delivery.

Introduction

The future for drug developers is defined by how effectively they adopt innovative strategies and new technologies, while navigating industry challenges and complexities. Sponsors must be able to stay abreast of emerging innovations, technologies and frameworks–and implement them appropriately–to facilitate successful development and delivery of therapeutics to market. Biotech and biopharma companies often use FSP outsourcing models to implement these new and innovative strategies more effectively–and keep their projects on schedule. FSP models have also proven to be a highly effective approach for realizing efficiencies via increased resource flexibility; tapping into global expertise and talent more productively; and accessing specific skills not available in house.

To enable drug developers to stay a step ahead, the PPD clinical research business of Thermo Fisher Scientific publishes *The Pulse*, our annual survey of 150 leaders at pharmaceutical organizations around the globe. *The Pulse* assesses trends in drug discovery and development, including preferences around outsourcing, FSP utilization and projected outsourced activities.

Deriving from *The Pulse*, our 2024 FSP trends report clearly shows that the industry is increasingly relying on FSP partnerships and hybrid approaches that blend full-service outsourcing (FSO) with FSP partnerships to manage the complexity of implementing clinical trial innovations. As companies more eagerly adopt these partnerships, FSP providers are likewise becoming savvier in driving transformation and efficiency through global collaboration models and optimized FSP strategies that enable clients to meet timelines more consistently.

Our 2024 FSP trends report serves as a roadmap for drug developers in a dynamic pharmaceutical landscape. Use this as a guide to:

Understand the latest utilization and growth projections of various outsourcing models in clinical research.

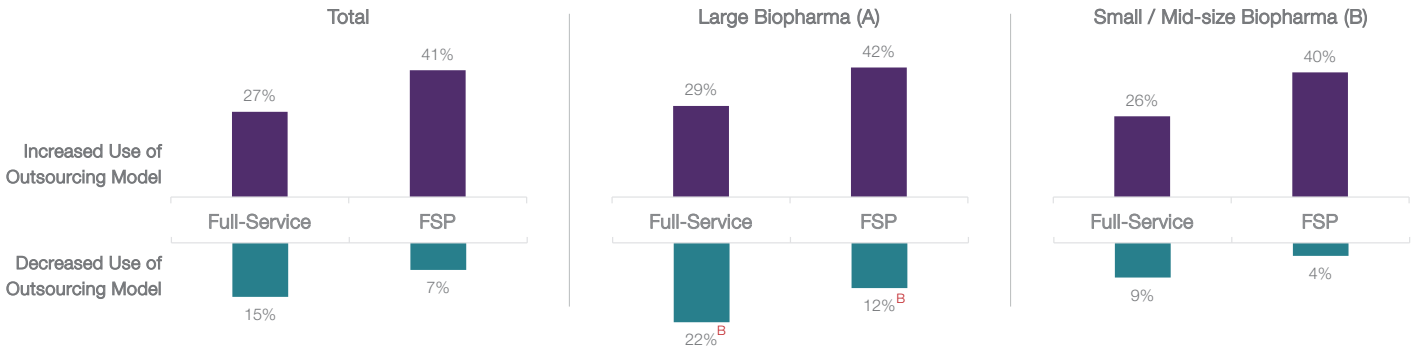
Ensure you're maximizing your outsourcing approach with future-facing FSP strategies and innovations.

Leverage our keys to success to ensure on-time, on-budget FSP delivery.

The rate of FSP growth as compared to FSO

FSP outsourcing is growing faster than FSO in all regions surveyed (North America; Europe, the Middle East and Africa; and China) and among companies of all sizes. More participants have upped their use of FSP outsourcing (41%) than those that say they have increased their use of FSO (27%).

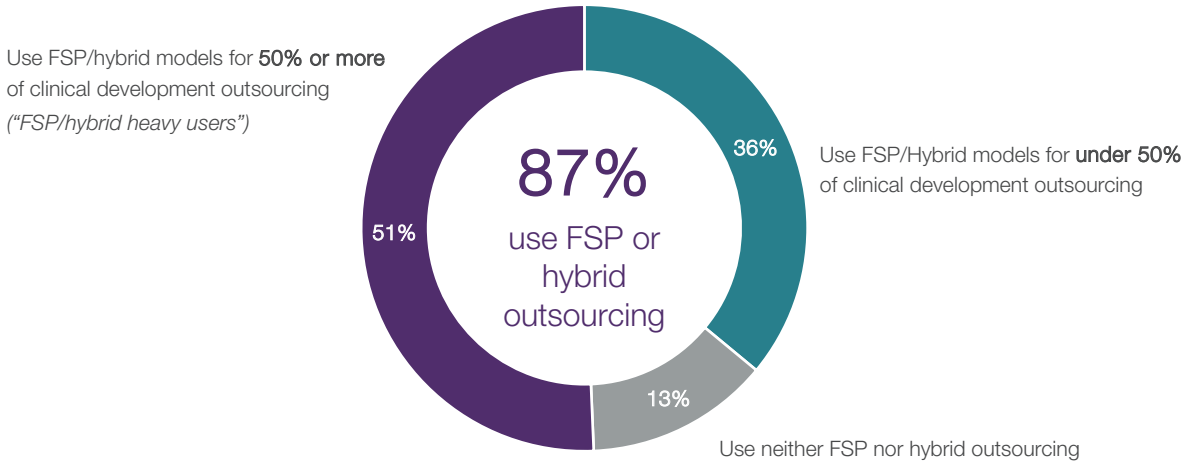
Change in use of full-service and FSP models compared to two years ago



Use of fsp and hybrid FSP/FSO outsourcing models

FSP and hybrid FSP/FSO outsourcing models are widely used–almost 9 out of 10 participants report using one or both. Half of participants indicate they are using FSP or hybrid FSP/FSO models for the majority of their clinical development outsourcing, which this report refers to as "heavy users" of these outsourcing models.

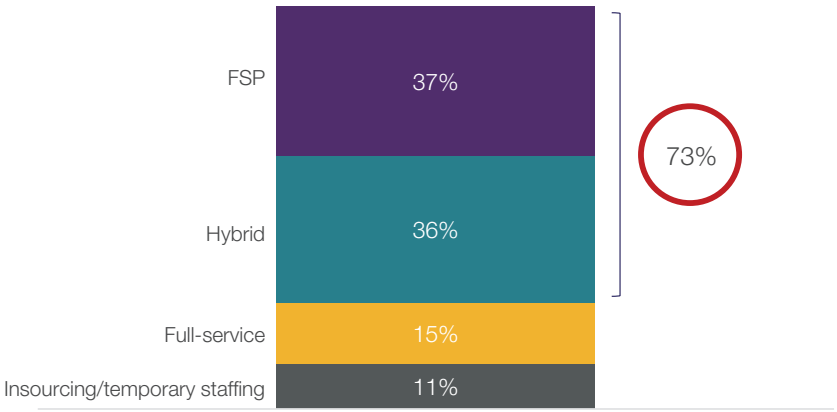
Use of FSP and hybrid FSP/FSO outsourcing models



Outsourcing model share and preference among heavy users of FSP and hybrid FSP/FSO models

Heavy users leverage these models for nearly three-quarters of their outsourcing.

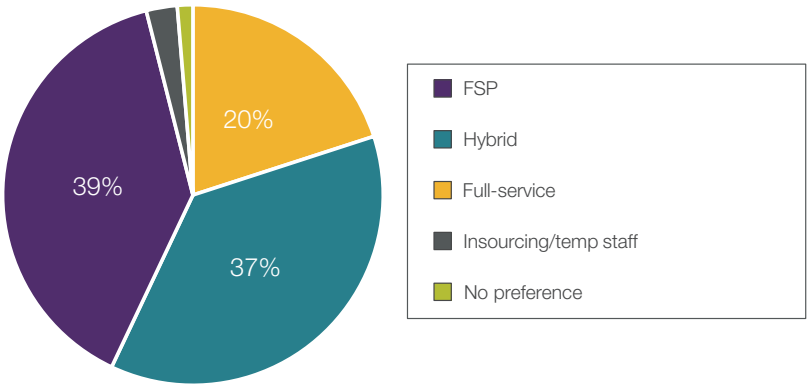
Outsourcing models share of current clinical development work



Hybrid FSP/FSO heavy users

Heavy users are evenly split when it comes to a preference for FSP or hybrid FSP/FSO outsourcing models.

Most preferred outsourcing model for clinical development



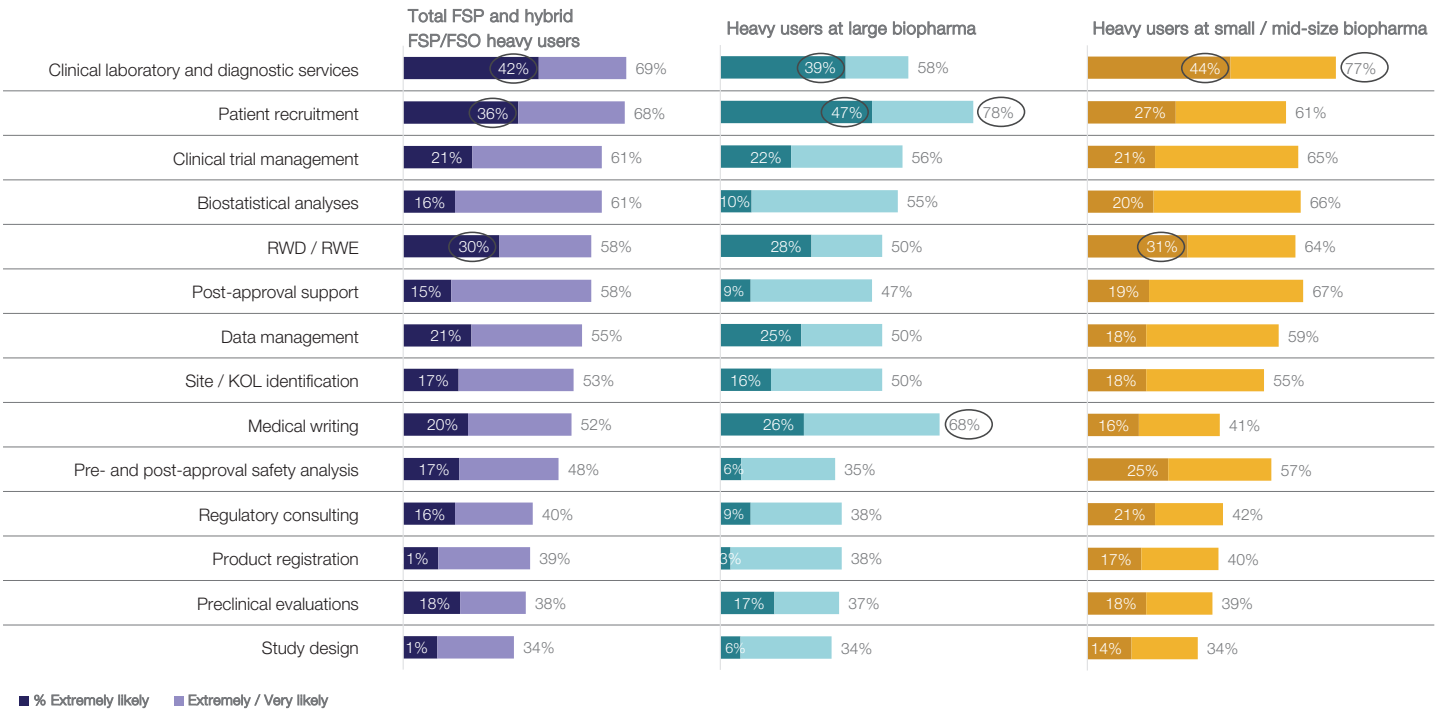
Hybrid FSP/FSO power users

Outsourcing of drug development activities

FSP and hybrid FSP/FSO heavy users expect their outsourcing to encompass a wide variety of drug development activities in the next two years, particularly clinical laboratory and diagnostic services and patient recruitment.

- For heavy users at **large biopharma companies** (those with an annual R&D spend over $1 billion), patient recruitment and medical writing top the list of activities likely to be outsourced, followed by clinical laboratory and diagnostic services.
- For heavy users at **small/mid-sized companies** (those with an annual R&D spend below $1 billion), clinical laboratory and diagnostic services lead the list, followed by myriad other services for which they are also quite likely to seek external assistance.

Likelihood to outsource drug development activities in the next two years



The future of FSP strategies and models

As more drug developers leverage FSP and hybrid FSP/FSO outsourcing models, new movements have emerged that progressive FSP providers are implementing to propel efficient, on-time delivery of sponsors' projects. For sponsors looking to get the most out of their FSP engagements, these optimizations, and adapted applications of the FSP model are critical to on-time, on-budget delivery. They are built around efficiency, strategic talent resourcing, global collaboration and cost-effective resource management.

- **Bespoke recruitment strategies:** A bespoke talent delivery strategy for FSP engagements combines the advantages of traditional full-service outsourcing and FSP recruitment models and takes a two-pronged approach to staffing. It draws from the internal pool of staff with various skills and uses proactive, external recruiting methods, while ensuring every candidate selected is an ideal fit for the job. Bespoke recruitment strategies for FSP engagements aim to improve efficiency by narrowing down the list of candidates before presenting them to the sponsor. This not only saves time, but also instills trust and confidence that the selected candidates are well-suited for their roles, reducing the risk of mismatches.
- **Established operations in global locations:** FSP partners that offer global resourcing across time zones enable sponsors to maintain operations around the clock and tap into resources in regions such as Asia-Pacific, Latin America, and parts of Europe, Africa and the Middle East. Companies that are based exclusively within North America and/or Europe, for example, can only access a fraction of the potential staff that would be made available by global outsourcing. The advantages of FSP partnerships with an expansive global footprint include resource flexibility, quality assurance, and efficient project management across time zones. Resource flexibility, in particular, facilitates sponsors in expanding their capabilities and reaching global markets to drive efficiencies and meet timelines.
- **Follow-the-sun models:** Time zone differences have historically been seen as a drawback in global outsourcing. However, well-established worldwide operations can turn this into an advantage for sponsors by providing a reliable point of contact to drug developers, even outside of local working hours. Applying the follow-the-sun (FTS) model to FSP engagements also ensures that support and responsiveness are readily available, regardless of time or location. This minimizes the risk of bottlenecks or delays due to limited working hours and maintains business continuity by reducing the risk of disruptions in a single location. The characteristics of clinical development and post-marketing surveillance make them especially suitable for FTS deployment, given the global collaboration, real-time data analysis, follow-up patient monitoring and global regulatory compliance required.

Application of the FSP model to expand into non-footprint countries

FSP models are increasingly popular for expanding clinical research operations into countries outside a client's geographic footprint, where companies can access local expertise, mitigate regulatory risk and extend their global reach. By leveraging FSP support to expand their global reach, companies utilize resources more efficiently, access a diverse participant pool and capitalize on the expertise of local professionals to keep operations on time and on budget. This is particularly valuable to proactively support developers in feasibility assessments and regulatory submission requirements, avoid competition for patients and sites, and promote synergistic operational excellence across key clinical research goals.

Keys to success in FSP partnerships

The 2024 trends show that FSP outsourcing is growing at a faster pace than FSO, which makes having the right FSP partner a critical decision point.

A strong FSP partner enables pharmaceutical developers to navigate the evolving landscape of the biopharmaceutical industry; leverage new, future-focused strategies and innovations in FSP project delivery; and ensure successful clinical development programs. Together, these capabilities, insights and expertise will keep drug developers ahead of the curve:

- **A track record of on-time delivery and extensive breadth and depth of expertise.** The right FSP partner recognizes that meeting timelines is the most critical element to advance clients' therapies, and will therefore build flexible, tailored solutions to achieve each client's goals. This starts with a breadth and depth of expertise that delivers the right experience and knowledge to fill immediate resource gaps, and dedicated roles focused on rapidly ramping up engagements to ensure projects launch on time and stay on budget. These requirements must be backed by a skilled team and effective recruitment and training processes, ideally with dedicated FSP recruiters and turnover rates that beat the industry average. To further ensure timelines are met, an FSP partner with global recruitment capabilities is vital, given the competitive demand for global talent in clinical research.
- **A strong approach to launch new partnerships and ensure collaboration throughout the engagement.** As FSP and hybrid models are used by nearly nine out of 10 drug developers, the implementation and operationalization of a new FSP partnership is increasingly important. Launching a new FSP partnership requires coordination and planning that is aligned to your goals. Clients often navigate various expectations, change management, shifting priorities and dynamic project/portfolio requirements. The right partner will provide professionals who focus exclusively on launching your project and supporting your evolving needs, from proactively planning and strategizing to enable a seamless kick-off to overseeing the duration of your FSP engagement as an extension of your team. Other key considerations include dedicated leadership, skilled capabilities aligned with your portfolio needs and a collaborative foundation of training and development, all driving efficiencies over time.
- **Proficiency in developing a bespoke recruitment strategy for your FSP engagement.** Different clinical research projects have varying goals and staffing requirements. As drug developers outsource specific functions, it's important to work with an FSP provider that creates a customized recruitment strategy for your FSP engagement, matching talent to your project goals. A bespoke talent delivery model for FSP engagements that combines the agility of the traditional FSP provider along with a deep internal talent pool is the hallmark of an FSO arrangement, and it yields a highly targeted group of potential staff for sponsors to choose from.
- **Substantial global capabilities that make FSP models more efficient.** Today's drug development landscape offers new possibilities for sponsors to tap into worldwide resources to maximize budget and timelines. FSP providers with dependable global capabilities provide sponsors reliability, as well as convenience. The follow-the-sun model, for example, relies on international talent to hand off projects so they progress no matter the time zone, while established operations in cost-efficient regions are more budget-friendly for clients and provide ultimate resource flexibility. Since each FSP engagement is tailored to the client's unique needs, expanded global capabilities provide greater options to achieve on-time, on-budget delivery.
- **Proven ability to expand clients into non-footprint countries, to access in-country expertise and mitigate risk.** Maintaining a business presence in every country is not feasible for drug developers, which is why a strong FSP provider will assist clients in expanding into countries outside of their geographic footprint to meet budget and timeline needs. From culture to quality management, the FSP provider irons out the details. This can include forecasting enrollment in certain countries or regions of interest based on local expertise and experience. In addition, a strong FSP provider will partner upfront to define key performance indicators (KPIs) and quality standards for the work to ensure the FSP services meet expectations and maintain high-quality standards in non-footprint countries.

We forecast what's next, so you stay ahead

Our 2024 FSP Trends Report illuminates the pharmaceutical landscape's shifting dynamics, emphasizing the pivotal role of FSP arrangements. Key trends reveal a significant surge in FSP outsourcing, outpacing adoption of traditional FSO across regions and company sizes. The current and future state of FSP outsourcing signifies a strategic shift, with drug developers increasingly favoring FSP partnerships and hybrid FSP/FSO models. This shift is propelled by the need for enhanced resource flexibility, global talent acquisition and efficient access to specialized skills so that pharmaceutical product development stays on schedule.

The evolving FSP strategies, such as bespoke recruitment, follow-the-sun models and globalized operations, showcase the industry's adaptability to overcome challenges. Success for drug developers in this dynamic landscape hinges on choosing the right FSP partner. A strong FSP partner demonstrates a track record of on-time delivery, extensive expertise and a tailored recruitment strategy. Launching and operationalizing new partnerships, along with proficiency in global capabilities and assisting clients in expanding into non-footprint countries, are critical success factors.

Success for drug developers lies in strategic collaborations, innovative FSP models and a keen focus on on-time, on-budget delivery. **As a result of our experience and breadth and depth of expertise, PPD™ Functional Service Partnership (FSP) solutions deliver by helping our clients meet their timelines**. PPD FSP solutions has supported nearly 300 clients, including nine out of 10 top pharma organizations, over the past five years. Backed by a 25-year legacy of FSP support for clinical and marketed products, we know what it takes to deliver customized solutions tailored to the unique needs of each client, providing much-needed resource flexibility, reliability and continuity.

PPD FSP solutions facilitate successful product development for partners, big and small, and in doing so, help accelerate the next generation of life-changing therapies.

Work with an FSP provider that sets the trends. Tap into the expertise of PPD FSP solutions today.

Methodology: The Pulse is an annual survey conducted by the PPD clinical research business of Thermo Fisher Scientific. We surveyed 150 participants, director-level or higher, at pharmaceutical, biopharmaceutical or biotechnology companies in March/April 2023. Participants worked in roles related to drug development at companies with at least one compound in development. Geographies surveyed were Asia, Europe and US/Canada. Large organizations, with annual R&D spend of $1 billion or more, comprised 43% of respondents, while small/mid organizations with an annual R&D spend of less than $1 billion comprised 57% of respondents.

Learn more at **PPD.com/FSP**

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