

Strategic Resourcing Using a Functional Service Provider (FSP): A Solution to the Talent War

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Introduction

As the pendulum swings between outsourcing and resourcing models, functional service providers give pharmaceutical, biotech, and medical device companies access to top talent who can be deployed as dedicated teams, providing resourcing agility, performance efficiency and overall cost savings.

It is no secret that there is a talent access problem today across multiple industries, and life science companies are not immune to this problem. There are more roles to fill than qualified people to fill them. More than 70 percent of life sciences CEOs say they are worried about key skill shortages, and more than two-thirds report difficulty recruiting talent with the skills they need. The cost of recruiting is high, and the time to fill key positions can cause project delays, slow trial ramp-up and close-out processes, and add significant internal costs and uncertainty throughout the product development lifecycle.

The talent shortage becomes more complicated due to shifting project priorities and growing pipeline needs. Sponsor companies often need to ramp up teams quickly, some for only a limited time, running the risk of having to lay off good people or keep talent on the books that are not needed for a period. Alternatively, using contractors introduces co-employment risk and the need to release contractor resources within 12-18 months due to term constraints leads to a loss of corporate knowledge and puts an added burden on internal staff to administratively and operationally manage these workers, which ultimately steals time from key initiatives. Both approaches can damage Sponsors' talent brand for future recruiting and add burdensome benefits, payroll and inefficiency costs to the budget. An FSP model provides the Sponsor with improved talent retention and no time limits, and career path options while mitigating co-employment risk.



Some Sponsors have addressed an internal shortage of expertise by fully outsourcing to CROs, which involves teams performing tasks and services in support of clinical research projects. While remaining a very effective option today, some Sponsors feel limited by a project-by-project approach, as some perceive this model to restrict agility, forfeits a degree of Sponsor control, and reduces some level of performance efficiency across multiple projects.

As an alternative, Sponsors who have a robust volume of outsourced work are moving to a Functional Service Provider (FSP) model in which talent is dedicated to that sponsor and their long-term outsourcing needs.

FSP models offer Sponsors solutions that answer the need for talent on demand with the right expertise at the right time while also improving functional efficiencies, agility and focus on internal needs.

Project teams that are assigned study by study are often composed of individuals who are supporting multiple clients. In this case, the CRO sets the work assignments and may need to adjust a project team to accommodate other priorities, creating unintentional project disruption. Some sponsors may feel as though this creates a loss of insight into the application of resources.

Moreover, outsourcing by project and via a request for proposal (RFP) process hinders resources from supporting one client across multiple studies as resources within the CRO model are typically assigned "just in time and following project award."

As an alternative, Sponsors who have a robust volume of outsourced work are moving to a Functional Service Provider (FSP) model in which talent is dedicated to that sponsor and their long-term outsourcing needs. The main benefits of this model include the Sponsor's ability to maintain control while functional teams focus on mastering the function and customizing the operational approach specific to the Sponsor, having a team dedicated to the Sponsor that can work across multiple projects and tasks, better employee recruitment and retention results, and cost savings through



pricing and efficiencies. Moreover, the burden of recruiting, hiring, and managing the talent sits with the FSP provider, allowing the Sponsor to focus on strategy and top priorities while maintaining control of the projects. The FSP provider is focused on operational execution with quality deliverables.

Part 1: Alternative Option—Outsource By Function

With an FSP, Sponsor companies outsource their talent needs to cover a range of functional needs whether it is the entire function or a set of specific tasks within a function. FSPs occur most frequently within clinical trial management, eTMF, clinical monitoring, data management, biostatistics, programming and pharmacovigilance. Essentially any function or task supporting clinical research can utilize the FSP model. Each Sponsor can determine the area they most need expertise, technology, or processes for developing an FSP for infrastructure, resourcing, management and quality project delivery. The Sponsor can decide where and how to utilize these resources and can rely on the FSP vendor to recruit, hire, and onboard the talent, assign workload, and monitor employee performance to ensure quality deliverables.

An FSP provides the Sponsor with virtually the same experience as having their own employees, without the cost, risk and ramp-up of recruiting these experts themselves. The FSP model brings additional value-add through systems, tools and strategic guidance.

Implementing a More Efficient Outsourcing Model

FSPs provide a more efficient way to outsource, saving time in your vendor selection process and reducing the effort required to manage vendors. Below are benefits for vendor selection and management when using the FSP model.

The amount of time and energy that goes into a “study-by-study” selection process creates a significantly larger amount of work for both the Sponsor and the service provider.

In an FSP model, the service provider delivers a dedicated team of people who work only for that Sponsor. The Sponsor may dictate the size, skills and experience level of the team, and then can use those resources with great flexibility for as long as needed.

FSP MODEL

DEFINE NEEDS BY YEARLY PIPELINE

- One Vendor Selection Process by Function Across a Portfolio of Studies
- One Bid Defense with One Group of Decision Makers

SET UP INFRASTRUCTURE

- Dedicated Team Across Projects with Flexibility
- Sign One Long-Term Contract Across Programs
- Limited Change Orders: Only to Add Staff as Needed

RETAIN TEAM, CREATE EFFICIENCIES, MEASURE

- Retain Employees; No Resourcing by Project
- FSP Plan, Resourcing Needs, Customized SOPs
- Volume Creates Efficiencies, Measure KPIs for Performance



This model delivers time and cost savings. FSP vendors who have a recruitment engine and database internally can typically ramp up a team faster than internal recruiting efforts. Further, because the vendor handles all recruiting, payroll, benefits and other employment infrastructure, it can lower costs and eliminate unexpected expenses like the cost of firing a bad hire or filling a sudden talent gap—not to mention greater access to a larger set of skillsets that can be used to fill gaps the Sponsor may have with their own team.

Sponsors Choose FSPs for Flexibility, Ability to Build Their Own Team

Once on board, there are no limitations related to which projects FSP resources can work on or on the length of the contract. In the FSP model, the Sponsor is free to move resources at their discretion. FSP staff can be dedicated to a single project or functional area, or support multiple projects and teams, and can be reassigned as needs arise. This often results in lower costs that charge task by task, rather than the dedicated resource. On the other hand, FSPs can be unit based and still maintain a dedicated team. FSPs often offer an incentive to lower, long-term costs due to a committed volume of work. Due to the greater flexibility offered by the FSP model and the ability to respond to fluctuations more quickly in workload, the FSP model minimizes the need for unexpected change orders.

Sponsor needs dictate how these resources will work within FSPs, including what technology platforms they use and the standard operating procedures they follow.

BENEFITS OF AN FSP MODEL

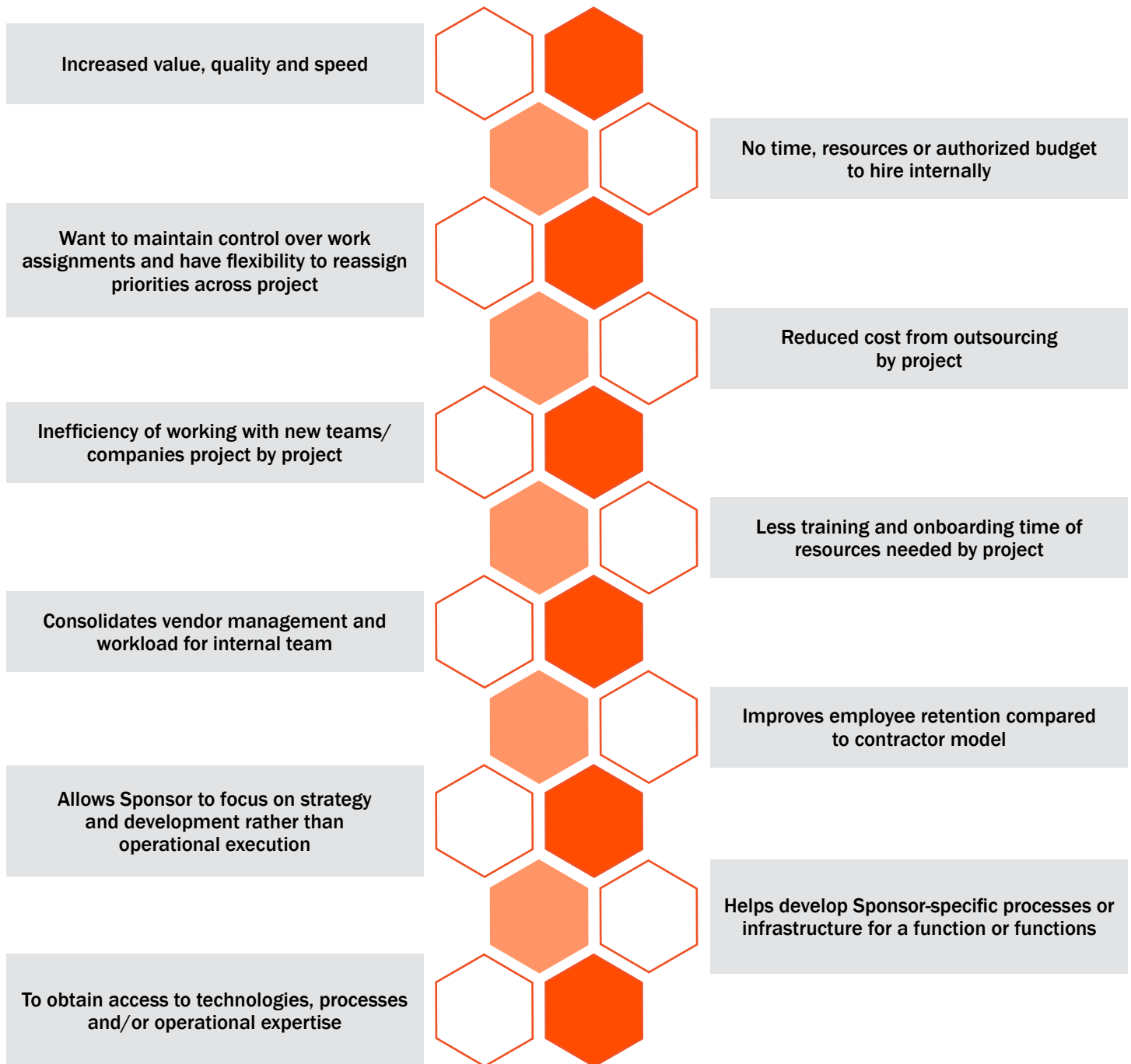
- ☒ Providing an outsourced function that becomes part of your team and includes built in management of that function including performance management
- ☒ Cost savings, financial consistency and predictability
- ☒ Less risk, Sponsor maintains control: Dedicated teams provide increased quality and compliance while allowing for adjusting timelines and priorities
- ☒ Reduced internal overhead costs: no need for additional internal recruiting, accounting, HR
- ☒ More time to focus on strategy, less vendor management
- ☒ Improved talent retention with no time limits, mitigating co-employment rules and career path options defined in FSP plan
- ☒ Ability to scale resources up/down to accommodate cyclical needs
- ☒ Dedicated teams, approved by Sponsor, only working for the Sponsor
- ☒ Training/onboarding can be handled by the FSP vendor as desired
- ☒ Creation of standards and repeatability of processes, ultimately increasing quality, reducing time, and creating efficiencies
- ☒ All SOPs and standards become the Sponsor's customized approach to business, allowing Sponsors to bring function in house in the future if desired
- ☒ Dedicated team is performance-managed by FSP Vendor
- ☒ Meaningful governance providing transparency, metrics, satisfaction measurement
- ☒ Choosing a Partner vs. Vendor, becoming a true extension of the Sponsor team



Part 2: Easing the Transition

The FSP outsourcing model can deliver measurable time and cost savings; however, as with any outsourced relationship, these resources need to be integrated into the company and given enough guidance and support to thrive. When Sponsors dive into FSP solutions without considering how these resources will function day-to-day with the internal team and other vendors, it may create internal conflict that impedes productivity. With simple planning, these risks can be limited.

TOP REASONS SPONSORS CHOOSE FSP MODELS





Strategy, Culture, and KPIs

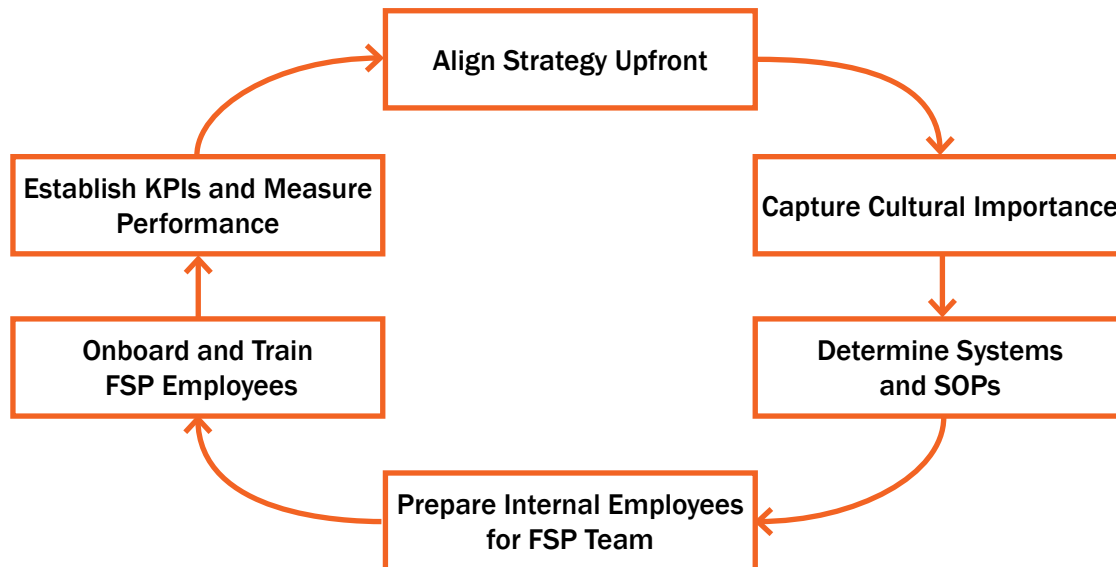
FSPs work best when Sponsors spend time up-front with their FSP vendor to define specific talent needs and ensure the outsourced team can be effectively embedded in the existing corporate culture.

When considering an FSP, decision-makers should first define how an FSP aligns with their business strategy. Ideally, the FSP vendor will spend time to thoroughly understand the organization's needs within a function and across functions. These insights will determine where and how FSP talent can

challenges from in-house teams who feel threatened by their presence.

Sponsors can prevent this kind of conflict by preparing managers and staff for the change, assuring their continued employment, and advising them about where and how these new resources will add value. Some Sponsors consider including specific employees in the process to select and onboard FSP team members.

Once on board, the Sponsor and FSP vendor will collectively



deliver business benefits and generate a transition plan for the best results. The needs analysis process is an easy, quick, already-defined process that aligns the goals of the FSP with the needs and preferences of the Sponsor. This decision process includes filling any talent gaps and project management capacity issues. A strong benefit of an FSP is the ability to not only provide a solution but to manage that solution on behalf of the Sponsor.

Once the needs are fully defined, the Sponsor can make decisions about how and where the new resources will work. From a technology standpoint, some companies prefer FSP staff use their internal platforms, applications and SOPs; others will leverage the FSP vendor's systems, or a combination of the two approaches can be utilized. Sponsors will also determine whether the staff will co-locate with in-house teams, work out of the vendor's offices, work remotely, or some combination of these options.

When Sponsors help the FSP vendor better understand the culture, attitude and overall workplace environment, the FSP will be much more effective. Many studies have shown that cultural fit and personality are highly predictive of job success. Cultural fit risks can be even more prevalent when bringing in outsourced talent who may face additional

establish key performance indicators (KPI), track performance, and assess whether project goals are being met. KPI data ensures the resources are meeting quality expectations, helps managers proactively identify issues or concerns, and helps decision-makers validate the benefits of the FSP investment.

Preparing staff for the change and creating space for these new resources to succeed is how smart companies generate the most value from an FSP environment.





Conclusion

FSP is the Solution of the Future for Sponsors with Healthy Pipelines

Sponsor companies struggling to identify the right talent at the right time can leverage FSPs in a number of ways to increase value, quality and speed while reducing risk and cost. An FSP model will help Sponsors quickly close resource and skillset gaps, improve standardization and efficiencies, and maintain as much control as desired within a function or functions.

The FSP model addresses many of the short-term talent attraction and retention issues that Sponsor companies face and offers a long-term strategy for managing a more scalable and diverse workforce. In addition, Sponsors that are spending a large amount of time and money preparing RFPs, analyzing proposals, attending bid defense meetings, and spending too much time on vendor selection and vendor management have a new solution—the FSP Model.

Sponsors considering an FSP model should look for vendors with a proven track record of FSP delivery and a willingness to spend time to understand the overall business needs and cultural environment. For an FSP to be successful, the FSP vendor must have a strong database of talent along with a powerful recruiting engine. FSP vendors should also have a defined plan for managing the FSP solution through KPIs, KQIs, incentives and systems for sharing this performance data as part of the contract.

When Sponsor companies treat their FSP vendors as strategic partners and work together to manage and monitor performance, they generate better, faster results that can be directly tied to project and business success.

Since talent shortages in the life science industry are not going away, companies will need to find more agile staffing solutions to meet deadlines, drive innovation, and maintain knowledge capital through better employee retention. FSPs offer a valuable solution to these challenges, giving companies the talent, support and performance, they need to meet their business goals.





Caroline Redeker

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Caroline is a results-oriented professional with 28 years of clinical research experience. She is currently responsible for driving innovation and brand expansion, creating new service offerings, and building corporate efficiencies for Advanced Clinical. She has worked within multiple contract research organizations, led and grown business development and marketing teams, budget and contract teams, and patient recruitment teams. She has also worked directly with customers on hundreds of clinical programs and developed many long-term, strategic customer relationships. Caroline is consistently driven by the perspective of the customer and is passionate about delivering exceptional service and an overall better clinical experience for every program. Caroline received her bachelor's degree in Finance and Management from Central Michigan University.

Stacey Arrambide

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Stacey Arrambide, M.S., Senior Vice President, Functional Solution Services, has over 21 years of global clinical development experience across a broad range of therapeutic areas. Stacey oversees strategic growth and operational delivery of FSP engagements for Advanced Clinical. He has held numerous leadership positions of increasing responsibility over various functional areas for Advanced Clinical and other CROs including being the Managing Director of a 150+ employee FSP. Stacey is a graduate of Sam Houston State University with both a bachelor's degree in Mathematics and a master's degree in Statistics and has contributed to and published numerous articles.



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