

The Evolution of Functional Outsourcing

Changes can benefit sponsors and partners alike

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MORE THAN EVER, THE INCREASINGLY competitive environment presents sponsor companies with the challenge of revolutionizing the drug development process in order to deliver the safest, highest quality products in the most efficient and cost effective manner. We believe that clinical sponsors are best served by a solid outsourcing strategy that can overcome cost and speed factors, and for many organizations functional outsourcing — now at a more mature level — provides the best solution.

The Development of Functional Outsourcing

Let's begin by reviewing the origins and growth of functional outsourcing, including its strengths and benefits, before proceeding to a discussion of how sponsors and their partners are taking the concept to the next level.

Functional outsourcing is the outsourcing of specific individual functions to specialist firms, or "niche providers," as opposed to the outsourcing of an entire project to a full-service CRO to perform all trial functions. Actually, this concept is not unique to the pharmaceutical industry, appearing in literature related to such diverse categories as supply chain, HR and IT management. When we first began applying the concept of functional outsourcing to clinical research, we believed then (and still do) that it represented a logical and cost effective way to perform such functions as study monitoring and data management, resulting in cost savings, more efficient use of

resources and enhanced quality control.

Functional outsourcing provides sponsors with measurable benefits related to bringing projects back in-house, allowing them greater control and oversight of the overall development process as they outsource the execution of specific functions to specialist alliance partners.

The creation of partnerships allows the sponsor to maintain the control it needs while working with firms that bring unique and specific skill sets. And, with access to the same technologies and standard operating procedures as the sponsor company, partners become part of streamlined and consistent processes that yield greater efficiencies and quality outcomes.

The human capital implications are considerable. Functional outsourcing can result in a more predictable workload, as well as allowing for the planning, recruitment, training and assignment of fully dedicated resources, working only on that sponsor's studies. This in turn can generate higher job satisfaction and improved retention, yielding greater speed and quality, as well as lower training and other replacement costs.

With resources assigned on a functional rather than a project basis, staff can work across multiple projects. This creates a cadre of trained staff who can be reallocated as necessary,

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resulting in a highly scalable model that supports the effective launch of new projects and is transparent both to internal customers and investigators.

Functional outsourcing can also generate a number of cost efficiencies for the sponsor company:

- It creates a strong, highly experienced and reliable team that requires a lower ratio of internal management to outsourced resources.
- One outsourced professional — the site manager or CRA — can not only manage multiple sites, but often multiple studies at the same site, reducing or eliminating duplication of efforts.
- Regional monitoring models offer cost savings and efficiencies based on geographic alignment, reducing the time and expense of site-visit travel.
- Incorporating remote workers allows partners to tap into a broader talent pool, whether to compensate for a scarce local supply of staff or providing the ability to hire staff from lower wage areas.
- Training costs are reduced through improved retention and the ability to assign staff to multiple projects on a recurring basis.
- Establishing a long-term master service agreement reduces the need to identify and select vendors on a project-by-project basis, thus decreasing the time and cost associated with initiating individual studies.
- This arrangement enables the provider to negotiate more favorable rates for the sponsor based upon an expectation of future business as long as service level expectations are consistently met or exceeded.
- The sponsor's outsourcing professionals become increasingly dedicated to the strategic management of the relationship, with a focus on driving continuous improvement in the quality and cost-effectiveness of services delivered.

The Lessons of Functional Outsourcing

We believe functional outsourcing, while still in its relative infancy, has already yielded valuable lessons for sponsors and their partners. Incorporating and building on these lessons will yield even better results moving forward. Among the most significant lessons to date are the following:

The most successful functional partners are embedded within the sponsor organization.

This relationship is expressed in several ways:

- **Strategic:** The embedded partner is truly aligned with the sponsor's strategic goals — contributing to, participating in and evolving with the sponsor's progress over time.
- **Process and technology:** In the functional partnership, efficiencies are realized through consistency of processes and greater connectivity by leveraging common platforms.

- **Communications:** In the best relationships, effective communications exist not only between sponsor and partner, but also among functional partners, as all partners learn to establish common ground and speak the same language.

The most successful relationships involve the selection of a partner that is best in class by function.

In the early stages of clinical research outsourcing, relationships with providers were built almost exclusively around full project outsourcing, a method that emphasized a "jack of all trades" assessment when selecting among service providers. Functional outsourcing providers, on the other hand, are selected for unique capabilities within specific functional areas, providing sponsors the benefit of niche expertise based upon years of experience delivering within that area. It is this higher level of expertise that often positions niche providers to be more consultative and develop a strong strategic relationship with their sponsor partners.

Successful partnerships result in higher sponsor expectations for quality and efficiency, which in turn generates better results.

The relationship is less resource- and overhead-intensive than sponsors often experience with the full project outsourcing model. Staff are hired and trained specifically for each engagement, then fully dedicated to the sponsor's needs. This ensures that the talent matches the sponsor's requirements and means that a "bench" of staff resources doesn't have to be maintained in anticipation of the next project — a practice that has considerable impacts on overhead costs. The outsourced partner is assigned a mission and then held accountable for performance measured in terms of quality, compliance and efficiency. As providers prove themselves increasingly capable of delivering consistently high service levels, sponsors become more comfortable with this outsourcing strategy. This enables greater "provider ownership" for their functional area, allowing each party to focus more time and energy on their respective core competencies, ultimately leading to higher levels of collective performance and the realization of the full potential of the partnership.

Future Directions for Strategic Sourcing

Many large pharmaceutical companies are outsourcing increasing numbers of clinical research activities, and agree that functional outsourcing is the model most closely aligned with their strategic direction. However, this is an evolving model, with challenges still being identified, discussed and resolved, including the following:

- *Which functions should be outsourced and which should be retained?* As the concept becomes increasingly accepted and adopted, decisions need to be made regarding which activities and how much. In some sponsor organizations, the decision is being made to outsource all non-core competencies. Others are challenging themselves to reassess what they have traditionally considered their core competencies or looking for opportunities to enhance expertise in certain functional areas by leveraging a partner to handle a percentage of that work while retaining their own work-

force for the balance. Ultimately, the decision comes down to a determination of which approach affords the greatest competitive advantage in terms of cost, quality and speed.

- *Is functional outsourcing appropriate for all pharmaceutical companies?* Functional outsourcing is not a “one size fits all” strategy. Rather, the answer often depends on the size of the sponsor company, as a higher level of outsourcing by function requires the development of a “multiple provider” strategy. Sponsors must have the internal capabilities in place to manage these relationships not only individually, but collectively as well to ensure continuity of the work on an individual study level. Functional outsourcing also requires a long-term commitment in order to be successful, relying heavily on the development of trusting and productive relationships in order to achieve the true potential of this strategy which implies increasing mutual dependency of partners over time. Additionally, senior leadership must be committed to the strategy to ensure efficiencies can be realized through standardization of processes across various groups within the organization, many of whom may have been accustomed to working relatively independently with their preferred full-service outsourcing provider on their specific project(s).
- *How can the sponsor achieve greater connectivity with its partners?* Areas of opportunity include making an upfront investment of time and energy to jointly establish and clearly define effective working relationships and communications processes, information sharing, systems access/visibility and mutually agreed upon standards of service, including key performance metrics.
- *How can the sponsor achieve greater collaboration among its partners?* The most successful outsourcing partners embrace the concept of collaboration as a way to support the sponsor’s success as well as their own, and should take the initiative to replace competition with collaboration as they establish effective relationships with providers to whom their sponsor client has entrusted other functional responsibilities. Ultimately, decisions and actions should be driven by the determination of “What’s in the best interests of the Sponsor?” regardless of traditional competitive influences which may still exist “outside the partnership.” The sponsor should facilitate this effort by clarifying parameters for respective areas of responsibility in order to

avoid gaps or redundancies, then lead the effort to define processes which enhance communication and minimize opportunities for misunderstanding or excessive escalation of issues which should be worked out between providers. Finally, the sponsor should make clear their expectations — and subsequently recognize favorable performance to reinforce — that collaborative effort between providers is a key deliverable of the partnership.

Final Thoughts About Outsourcing Partners

Sponsors are increasingly looking to extend their relationships with their closest outsourcing partners, believing that it is easier to extend an existing partner’s relationship into additional servicing areas than it is to establish a trusting relationship with a new partner.

Other factors sponsors cite in their selection of partners include:

- Best-in-class status, with the expertise needed to jointly develop and implement the best possible solution now, as well as the foresight and initiative to recognize and adapt that solution to changing needs over time.
- A solid reputation and access to a pool of trained and experienced talent, allowing the provider to rapidly identify, attract and retain top quality staff within a particular functional area.
- A proven track record for service delivery, accompanied by financial viability.
- The ability to communicate effectively and productively with the sponsor organization and other functional partners.
- The ability and willingness to support additional functions which the sponsor may elect to outsource in part or whole in the future.
- Compatibility of values between the sponsor and partner to build a long-term relationship based on trust and exceptional service.

It’s clear that sponsors and their partners are now moving toward revolutionizing outsourcing practices in support of the drug development process. The maturation of functional outsourcing will continue to be one of the key elements in this revolution. ■

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