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RECRUITMENT & RETENTION – GETTING SPECIALIZED

By Melynda Geurts

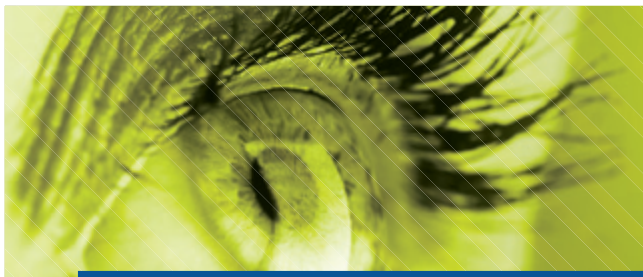
Although new outsourcing models have evolved in the life science industry, pharmaceutical, biotechnology and medical device companies continue to face adversity. As time passes, development steadily increases in both cost and time to market due to an array of demands ranging from stricter regulatory requirements to significant hurdles in patient recruitment and retention. Thus, the industry continues to explore new ways to leverage outsourcing to address such challenges.

For example, the estimated expenditure for a major pharmaceutical company to bring a new drug to market is in the billions USD, with clinical trials racking up costs in the hundreds of millions USD. A significant piece of this is due to the lack of fluidity in historic outsourcing structures, as they require multiple vendors and sponsor project managers (PMs) for each step, providing limited integrating management information to all PMs. Notable among the inefficiencies are: 1) the high degree of time required to administrate different processes among vendors, as there is limited management visibility and information for each sponsor PM; 2) the rising risks associated with dissimilar systems, variability and complexity; and 3) redundant transactions.

THE HISTORY OF FSPs

The traditional Functional Service Provider (FSP) model came on the scene as a strategic outsourcing paradigm that focused on aggregating a number of functions under one roof, allowing for more consolidated project management. This provides flexible solutions for improved efficiency and lowered overall costs. A scalable, expert team of resources is provided for a particular function, shifting priority to the clinical development task rather than the project itself. Here, various approaches are utilized to bundle services versus outsourcing a single capability to multiple suppliers in support of multiple projects or studies.

The traditional FSP model allows companies to separate core and non-core capabilities, and choose providers more specialized in specific disciplines. This removes the burden on internal associates, reducing day-to-day management requirements. Furthermore, the company benefits by retaining strategic control.



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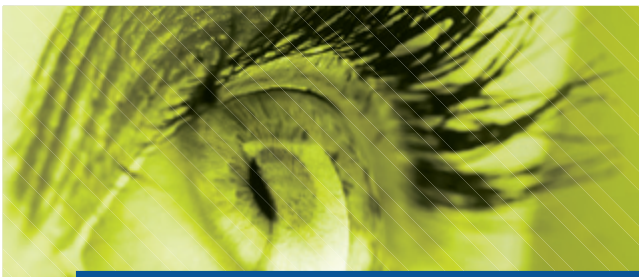
A key strength of traditional FSPs lies in their ability to convert time-consuming, complex business processes into streamlined activities with quality measurements. This, in turn, helps staff produce consistent, repeatable results every time.

However, potential drawbacks exist within the traditional FSP model, which often still requires the procurement of multiple vendors by the FSP for needs that extend beyond their core competency. Eventually, these multiple and preferred vendor relationships no longer deliver the FSP promise of increased efficiencies and cost savings. These drawbacks are commonly seen in clinical operations at the study management level in the areas of patient recruitment and retention, translation management, and study material production and fulfillment. Growing global complexity is not only increasing pressure on sponsors, but also testing the traditional limits of existing supply chains and vendor relationships, including the traditional FSPs that support them.

NEW SPECIALIZED FSPs EVOLVE

These drawbacks have spawned the emergence of new specialized FSPs. Take the following scenario for example. When developing strategy for a new trial, the following activities may need to be incorporated: patient recruitment and retention, creative direction, translation management, design to print formatting, proofing, make ready production, fulfillment, and global logistics. Typically, these activities would be sourced across multiple vendors using the traditional FSP model. This decreases time efficiency while increasing cost. The specialized FSP takes on a vertically integrated model that holds in-house strengths across multiple trial requirements, minimizing the need to outsource critical activities. This reduces the need for independent vendors, mitigates complications arising from dissimilar business systems, and allows for real-time management information, among other advantages. Additionally, there is a single point of accountability that minimizes vendor management and risk for the trial sponsor or CRO.

Patient recruitment and retention is a critical component of any clinical trial, and poses some of the greatest challenges. In many cases, a recruitment provider may play the role of a traditional FSP, having to handle multiple vendor coordination to gain competencies they don't possess organically. To reiterate the points previously made, this can cause delayed timelines, increased costs, and higher risk. When engaging with a recruitment provider that is part of a vertically integrated specialized FSP model, many of these challenges are averted. There is streamlined communication using one PM who initiates the project from start to finish across in-house competencies. This avoids issues among recruitment and retention project components such as creative services, translation and production. Communication from the single point of contact takes on new value as the contact is directly



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connected to the integrated companies servicing the project. This enables access to accurate, real-time project information for the CRO and/or sponsor, adding to greater control on their end.

To be clear, most companies outsource to some extent. The tipping point occurs when a specialized FSP garners and consolidates a major portion of what has remained traditionally outsourced and segmented among multiple vendors.

With a recruitment provider that offers the traditional FSP model, communication to the client regarding matters of managing contacts, vendors, metrics, and suppliers may be redundant. Depending on the scale and capabilities of the recruitment provider, other issues may arise, such as the financial burden of processing multiple invoices; costs associated with spreading work order issuance across multiple vendors; complications with regulatory submission of study materials being handled properly; and global compliance with value-added taxes (VAT), duties, and other taxes on study materials, which place the sponsor at high risk for fines if not facilitated by highly trained personnel. For sponsors and CROs, managing these risks requires their internal project management focus to be dispersed in unnecessary areas.

COST AND TIME SAVINGS ABOUND

With the specialized FSP recruitment provider, a range of unnecessary costs may be avoided depending on services being leveraged. Reductions may be seen in the areas of:

- Risk of non-compliance with state and local taxes, VAT, duties, and custom fees
- Shipment to parties denied by the U.S. government
- Administrative time devoted to reconciliation of activities
- Time allocated to manual checks to support site refund for duties and VAT
- Contract completions
- Vendor audit costs
- Project recovery costs if an FTE loss is incurred
- Multi-vendor dispute resolution time and costs
- Project management time devoted to regulatory submissions

By improving patient recruitment and retention with a specialized FSP model, sponsors and CROs are able to keep their PMs focused on study execution rather than vendor management. With the increased complexities in global trial management, having a consolidated resource with expertise spanning numerous trial components can deliver significant cost and performance improvements to a study.

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ABOUT THE AUTHOR

Melynda Geurts, M.S.
Vice President, DAC Patient Recruitment Services

Since joining DAC in 1998, Melynda Geurts has emerged as a driving force in the company's approach to project operations, site management, contract negotiations, and business development. A recognized authority in the clinical trials industry, Geurts has presented at numerous conferences and seminars worldwide. She is widely published and was a contributing writer for "Global Issues in Patient Recruitment and Retention" and "A Guide to Patient Recruitment and Retention," both published by *CenterWatch* in 2012 and 2004, respectively. In 2008 PharmaVoice named her among the *100 Most Inspiring People in the Life-Sciences*.

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