



Abstract

This paper, drawing on 60+ years of FSP management experience, will explore the strategic advantages to utilization of an FSP approach to biometrics work, including the customization available, setup, maintenance, and ongoing governance. The reader will better understand the difference between staffing and a service solution.



The Biltmore - Asheville, North Carolina

Introduction

Gardening Analogy

The Biltmore is a sprawling estate in Asheville, North Carolina built by George Vanderbilt from 1889 to 1895. It is currently 8,000-acres although the original acreage was approximately 125,000 acres and included property later sold to the federal government to create Pisgah National Forest.

The 250-room Biltmore House encompasses 175,000 square feet (four plus acres of floor space) including 35 bedrooms, 43 bathrooms, and 65 fireplaces. Adjacent to Biltmore House are 75 acres of formal and informal gardens designed by renowned American landscape architect, Frederick Law Olmsted.

As impressive as the Biltmore is, the gardens are what made a lasting impression when I visited a few years ago. They are filled with color, and plants that bloom in all the different seasons! I started thinking in terms of our industry; who cares for the gardens? Is it individuals hired one-by-one, or is it a dedicated team with the requisite expertise and a consultative approach? My educated assumption is the latter.

<https://www.biltmore.com/blog/10-fast-facts-about-biltmore/>
<https://www.aoc.gov/explore-capitol-campus/frederick-law-olmsted>

FSP in the Pharmaceutical / Biotech industry

As a homeowner, I can easily hire one person to care for my own “sprawling” grounds.

Similar, a small Biotech start-up may be able to get by with a staffing approach to their work, contracting one biometrics person at a time. As we’ll discuss later in this paper, there are advantages and disadvantages to this method.

A better solution for mid-to-large sized companies would be to employ the Functional Service Provider model for specific needs, be it statistical programming or biostatistics.

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Definition of an FSP

In short, an FSP implementation is a long-term contract with a uniform, consistent team & expected renewal at the end of the contract (assuming both parties are pleased with the ongoing relationship).

It is more comprehensive than simply staffing, and more specialized than outsourcing an entire study to a vendor in a less collaborative model.

There is a plethora of advantages to this model, the first being the transparency of the project work as the work is performed on the client systems. Intellectual capital is retained as there are no issues with co-employment.

In this poster, the terms “sponsor” and “client” are used interchangeably, as are “CRO,” “vendor” and “provider.”

Continuum models

Burt Baskin and Irv Robbins may have concocted 31 flavors, but there are an infinite number of varieties in FSP implementation!

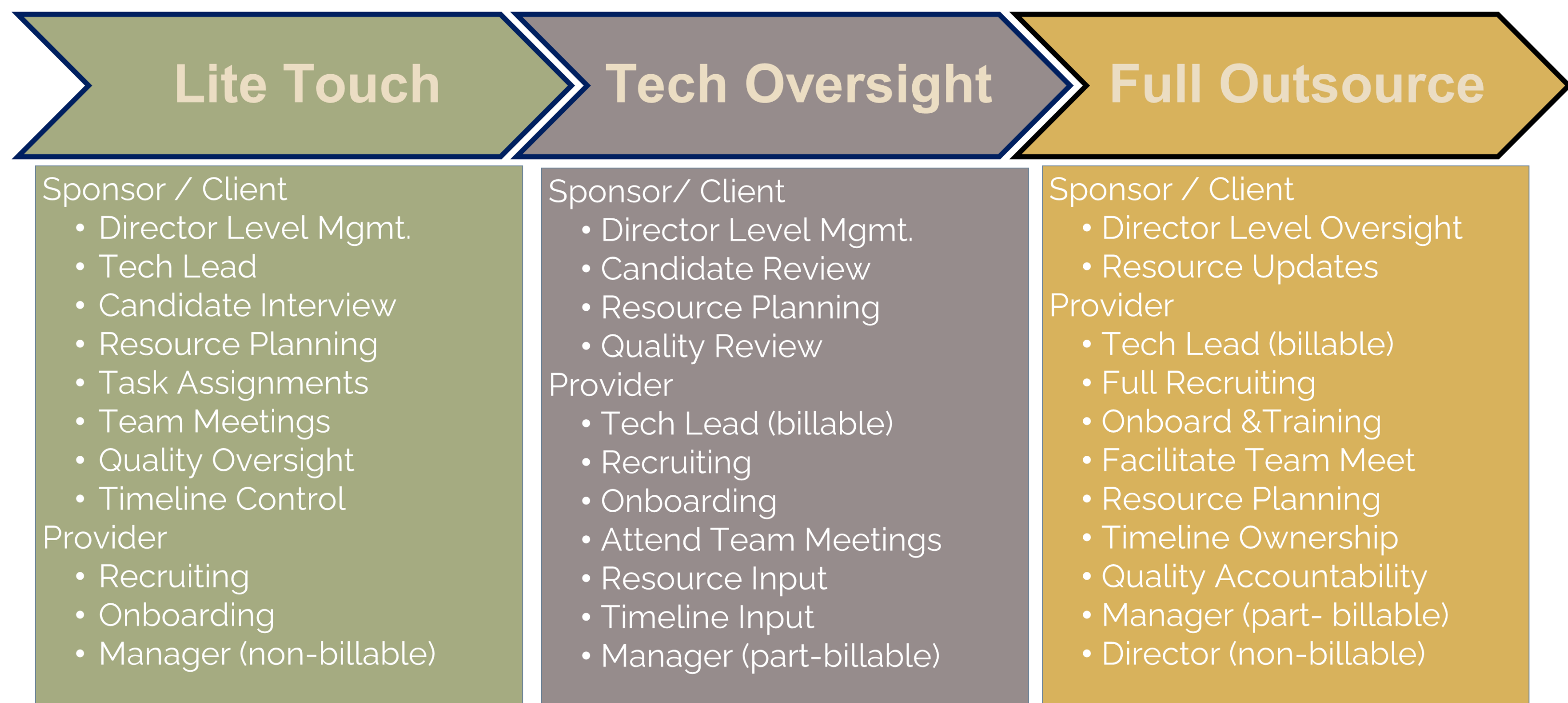
When first starting a relationship between a provider and sponsor, it is likely to appear closer to staffing than anything else. As one moves across the continuum, more responsibilities are shifted to the provider, including project management and accountability.

This movement can occur organically over time as the relationship progresses, or it can stay on any given point as determined by the client. For simplicity, we’ve divided the continuum into three sections. As we mentioned earlier there are no limits to the structure of the relationship.

<https://www.baskinrobbs.com/en/about-us>

The Functional Service Provider Model

A Comprehensive and Collaborative Solution



Lite Touch®

In this model, like staffing, the client maintains control of most aspects of the project. The provider is responsible for understanding the needs and recruiting suitable candidates. The provider will assist with onboarding and appoints a manager to maintain contact with the client and consultants.

Technical Oversight (Medium)

In the “Medium” model, some of the leadership and oversight, generally at a task level, are transferred to the CRO. It can be in the form of a Technical Lead, or a Lead Programmer/Biostatistician reporting to the overall sponsor project leads.

In addition, the provider has more ownership of the recruiting aspect. The client may review candidates, but not necessarily interview them. This is an indication of earned trust between the parties.

Full Outsource

In our final model, the provider has even more responsibility, allowing the client to focus on other projects with the knowledge that the vendor is acting as an extension of their own team.

This may look like a typical CRO model, and we’ll discuss this further on. The biggest difference is where the work is performed and maintained.

Advantages of an FSP relationship

There are many related advantages to both the sponsor and the provider in an FSP relationship.

Simplicity of Contract Maintenance

Contract maintenance is a pain point for both suppliers and providers.

By having all consultants dedicated to an FSP contract, the parties only need to deal with the contract every three years or so. In addition, the concept of a rate table can simplify contracts even further; all Sr. Statistical Programmers are billed at the same rate. Rather than having to track and verify rates for each consultant, there is a uniform pool of resources for the contract.

The importance of this cannot be overstated and is closely related to all the advantages of an FSP relationship.

Retention of Intellectual Capital

Can one think of anything more frustrating than losing a trusted consultant to a “time out” policy? After spending months training and acclimating a new team member, the clock starts ticking on how long a Sponsor can utilize a contractor.

One study showed that it takes up to five months before a contractor is fully onboarded. This long period is an investment on the part of both the sponsor and the provider, and not having to repeat this cycle continuously is a plus for the engagement.

<https://www.lexjansen.com/wuss/2008/mcp/mcp02.pdf>

Growth of Individuals

Closely related to the Retention aspect is the career growth of individuals. Because a consultant on an FSP engagement is not subject to a “time out” clause, they will likely stay on the project much longer than they otherwise would have. This allows the Sponsor to assign them more interesting and challenging work, and in turn, career growth.

An individual in an FSP can be promoted within an engagement rather than having to look for another position to try to gain a title change. This benefits all the parties involved.

Consistency

All these advantages emphasize the consistency of the dedicated team in an FSP environment. Resources aren’t shifted from another engagement as in a CRO model. Consultants are more engaged and will stay longer than they otherwise would (or could). Extensions of engagements are more straightforward, and the team stays in place efficiently.

While there will be always be some turnover involved, but there is likely to be more on the sponsor’s than the provider’s side, and certainly much less than industry average. If consultants see a career path with an engagement, they will probably continue with the same provider.

No Change Orders

One of the traditional challenges of managing a CRO is the issuance of change orders. When contracting on a project basis no agreement can be specific on all the changes encountered. Therefore, change order are an inevitable outcome of traditional outsourcing. In the FSP model the primary variable is the number of resources specified by the sponsor. The flexibility to increase or decrease resources is incorporated into the contract language. Thereby eliminating traditional change orders with the inherent challenges of agreeing on scope and cost which are a drain on sponsors management resources.



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Establishing an FSP

A Sponsor/Provider relationship has many of the same aspects of any interpersonal connection. With proper “care and feeding” the chances of long-term success increase.

Set expectations

The first item of business is to set open and honest expectations of each party. This helps to establish ground rules and a path forward for the work to begin.

This is not unlike working with an individual employee. With “clearly defined expectations, there is less confusion, more empowerment in their positions and a road map for the employee to succeed” (SHRM)

- Emphasize objectives.
- Set expectations early.
- Make each party accountable.
- Give meaningful feedback.
- Leverage motivation.
- Make it measurable.

Relationship Management Plan – a joint effort

“A **relationship management plan** is an organizational strategy of maintaining a level of engagement with its customers and other stakeholders.”

The RMP has many key elements, and is a living document created with input from both parties. It will include information such as:

- Organizational structures
- Stakeholder roles & responsibilities
- Escalation paths
- Communications matrix
- Meeting schedules and attendees

The RMP establishes the ground rules for the teams to work together, and the ongoing governance framework.

<https://www.shrm.org/resourcesandtools/hr-topics/people-managers/pages/setting-employee-expectations.aspx>
<https://www.projectmanagement.net/relationship-management-plan-template/>

Ongoing governance

Size of team

The number of consultants that begin an FSP is likely to be a small team. As trust is earned, the size of the team will grow. It’s important to keep in close communication with each other regarding short and long term needs to create the properly sized team.

Utilization report

One of the most important tracking mechanisms in an FSP relationship is the monthly utilization report.

This will detail the hours worked by each consultant in that month, and the projects the hours were applied to.

Even though the invoice will show a consistent amount from month-to-month, it’s critical to track actual hours. If a consultant is working overtime on a consistent basis, it’s fair to ask for an additional resource.

Conversely, if a consultant is underutilized, suggesting that the resources are rebalanced assists the client with their internal project management.

Metrics

Other metrics besides the utilization report are helpful to both parties and can be presented on a regular basis. Quarterly spend by project, as well as year to date spend, will help ensure that the sponsor’s money aligns with their corporate priorities.

In addition:

- Headcount over time
- Retention
- Resource Tenure
- Quality
- Timeliness
- Ramp up (success)

These metrics should show the value provided to the relationship.

Regular meetings – monthly / quarterly via zoom

The advent of Zoom and other video meeting platforms allows the management and operational levels to check in with each other as often as desired. A monthly meeting may be helpful at first, and as the relationship progresses, these can be moved to quarterly.

The metrics discussed above can be presented by the provider, and the sponsor can give operational updates.

Annual in person meeting

It is mutually beneficial to bring leadership together in person on an annual basis. These meetings are similar to the video meetings but will also be more strategic in nature.

Breakout groups with predefined agendas can discuss the upcoming year and make course corrections to the plan as needed.

Face-to-face meetings, including a group dinner, help cement a good relationship and set the tone for the future.

Conclusion

A successful FSP combines several elements working in harmony – strategy, retention, transparency, consistency, and governance. It is built on a foundation of trust and partnership. Each organization works towards the same goal – getting the sponsor’s products to the market as efficiently as possible.