

Selecting the Right Outsourcing Model for Emerging Biotech

Flexible outsourcing models help drive quality, control costs and enable better efficiencies and faster delivery.



Functional service partnership (FSP) outsourcing models traditionally have focused on supporting large pharma because they were the early adopters, whereas smaller pharma and biotechs tended toward full-service outsourcing (FSO) and contractors. Today, however, smaller and emerging biotech companies are able to take advantage of a range of flexible outsourcing models that help to drive quality, control costs and enable better efficiencies and faster delivery. This article discusses considerations for selecting a model and how more mature

resourcing models can be of particular value to biotechs when highly skilled people are needed.

In FSP, the traditional model involves full-time equivalent (FTE) based engagements where vendor staff is 100% dedicated to the client, working directly within client systems and standard operating procedures (SOPs). The needs of organizations vary, sometimes requiring dozens or even hundreds of dedicated FTEs around the world to support multiple trials with multiple protocols in client systems. On the other hand, biotechs in the early

OUTSOURCING MODELS

stages of development may prefer full-service outsourcing (FSO) support to execute one or two clinical trials, as well as a few key resources (FTE-based or hourly) to supplement their existing team as the company grows. Needs evolve as the organizations change, and so, too, should the model.

ASKING THE IMPORTANT QUESTIONS

There are two questions that help focus on how best to engage with potential FSP vendors:

1. Do you prefer to have fully dedicated people who integrate into your own team and systems? Or, do you prefer to pay by the discrete unit of work or task (e.g., per database built, monitoring visit completed or SAE case processed), using staff that is not dedicated to you?
2. Do you need partner staff to work directly in your systems (CTMS, eTMF, EDC, IXRS, EMS and so on) and SOPs or do you need the vendors to use their own systems and SOPs, or some hybrid mix?

There are no correct or incorrect answers to these questions—only what is best for your organization. And, what is best for you today may change over time as you move from pre-clinical into clinical trials, submissions, out-licensing or into market post-approval.

SEVERAL MODELS TO CONSIDER

In an FSO model, the biotech client typically sends the vendor a protocol and asks them to run the study. The work is most often done in the vendor's systems and SOPs. This turnkey approach offers multiple services for a single study and is designed for the least possible burden on client staff. The vendor's resources usually are not dedicated to the client.

The FTE-based model provides vendor resources that are 100% dedicated to the client, typically working within their systems and SOPs, perhaps in their offices and with their email addresses. Here, the client maintains overall study and/or project direction. This is a great choice for clients who need to supplement their own internal staff or expertise.

With a unit-based model, the client pays not for FTEs but for units of work delivered. The advantage of this approach is that work can flex up and down with clients' changing needs over time. It is important to note that in this model vendors most often use their own systems and SOPs, and vendor staff only will be 100% dedicated if the volume of work is large and steady enough to support full FTEs.

A mixed or hybrid model incorporates select elements of FSP and FSO in a bespoke manner, rather than a one-size-fits-all solution. This custom approach can look like a full-service model (multiple services), but certain key roles may be dedicated FTEs. Another option for biotechs features a mix of FTE-based for lead, key roles and unitized functions (site contracts, budgets, SAEs, etc.) for other services provided.

The following case studies for the three main FSP models—FTE-based, unitized and hybrids—show how these models are working in the real world.

Case Study #1: FTE-based model addresses need for rapid workforce increase

A European biotech urgently needed resources who could work across studies and flexibly transfer from one project to another as priorities shifted. Also, this client required staff who could work directly in their systems and SOPs.

Due to early scientific success, the client raised a large sum of funding in order to simultaneously support multiple assets with multiple trials. After initially seeking to directly hire permanent staff, they realized they could not find adequate qualified staff, did not have the management resources to on-board and train staff when they could attract them, and then did not have managers or systems in place to allow people to work remotely. In hindsight, this need for systems and support for remote workers became even more critical as COVID-19 shut down offices. Their reality was best served by an FTE-based model, which was able to be implemented rapidly.

An FTE-based model featured:

- Full-time staff located in countries across Europe and North America;
- Multiple roles including study management, clinical operations, data management, medical writing, etc.;
- Additional part-time flexible resources for regulatory and consulting support; and
- An executive governance structure to understand and address rapidly evolving needs.

Outcome: Currently at 20 FTEs and growing, the net result is reduced trial bottlenecks that have allowed the client to pull timelines back on track, while avoiding the direct costs and financial risk of hiring all of these people directly.

Case Study #2: Value in a unitized model for a rapidly growing client

A biotech client with a growing portfolio needed to rapidly expand to cover data management and drug safety services. They wanted centralized services in order to drive uniformity, improve quality via applying lessons learned and yield efficiencies from trial to trial to trial. The client had not invested in data management or safety case processing systems, and therefore needed a vendor partner with strong systems and SOPs. Work volumes were highly variable, with some months of high intensity and others low, following a normal ebb and flow of clinical research.

A custom unitized model featured:

- Custom-built units to address client preferences, yet be flexible for studies whether large or small, single-country or global;
- However, even in a unit model, volume was sufficiently high to support roughly 60% of the assigned vendor staff to be fully dedicated, whereas the other approximately 40% flexed on and off each month as volumes changed; and
- Direct collaboration with both the client and another CRO vendor.

“When considering FSP resources in the FTE-based model, many clients tend to think in terms of annual salaries only. With that in mind, when clients seek FTEs from vendors, they often get ‘sticker shock.’ While FSP resource salaries may seem like a relatively higher cost, it’s important to keep in mind the long-term cost of having your own people “on the books.””

Outcome: Client has a variable model that protects them from fixed FTEs that may or may not be 100% busy at all times. The vendor implemented a single master-contract solution, covering multiple trials under a single agreement, yet splitting invoices across seven, protocol-specific purchase order numbers, greatly reducing contracting, administrative and oversight for the client.

Case Study #3: Flexible, dedicated teams for a large program in a hybrid model

A client that traditionally used an FSO model wanted certain key team members dedicated from startup through database lock. They also wanted the flexibility to roll the dedicated team member from study to study. The solution was to build a hybrid model alongside their existing FSO, featuring:

- 100% dedicated on-site CRAs, remote CRAs, project assistants, data leads and project managers;
- The ability for dedicated staff to move from study to study; and
- Working in vendor systems and a combination of client/vendor SOPs.

Outcome: The program at its height included more than 20 dedicated FTEs, supporting four studies over three years, enrolling all four ahead of schedule and achieving database locks ahead of schedule.

THE BUSINESS CASE FOR FSP RESOURCES

When considering FSP resources in the FTE-based model, many clients tend to think in terms of annual salaries only. With that in mind, when clients seek FTEs from vendors, they often get “sticker shock.” While FSP resource salaries may seem like a relatively higher cost, it’s important to keep in mind the long-term cost of having your own people “on the books.” There are many facets to consider.

- Recruiting, hiring and training: Getting the right resources in the door and up to speed comes with many costs, especially when it comes to high-demand senior roles such as program managers, medical monitors and senior biostatisticians. Filling senior positions often requires outside help

from a headhunter. The standard headhunting fee is at minimum 20% of the employee’s salary, which means that acquiring just one resource with a \$100,000 salary will cost \$20,000.

- Compensation (base pay and bonus, if any) is well understood by managers, but benefits and employment taxes are often an equally large component of employee cost. Like recruiting and onboarding, the compensation package carries more cost with a more senior role, and is compounded when many resources are needed.
- Employee engagement and retention: Keeping your employees—and keeping them happy and productive—is critical to your company’s effectiveness. The key factor here is the size and effectiveness of your human resources function. A less visible factor is the cost of employee disengagement, which shows up as sick days, demotivation and ongoing poor performance.
- Replacement: When people leave the company, the entire employee lifecycle process starts over again. When turnover is high, it often has the side effect of demotivating other employees. Gallup estimates that the cost of replacing one employee is roughly 1.5 to two times the employee’s salary.¹
- Management: A “hidden” cost of having an employee is having someone more senior to manage that employee.
- Equipment and other overhead: The more employees you have, the higher your overall cost of doing business.
- And finally, your financial officers may wish to shift “fixed” costs (biotech employees) to “variable” costs (FSP vendors) as a way to reduce fixed debt on your books.

In this light, FSP resources, whether in the dedicated FTE, unit or hybrid models, are much more cost effective than they might seem at first glance. And they offer biotech companies the great flexibility to meet their rapidly changing needs across the drug development journey without the risk and efforts of internal hiring. **CP**

Reference

1. <https://www.gallup.com/workplace/247391/fixable-problem-costs-businesses-trillion.aspx>