Embracing a Functional Service Partnership Model for Rapidly Growing Biotechs

A tailored functional service partnership model can provide biotechnology companies on the cusp of significant growth, with the expertise and flexibility they need for successful development and delivery

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Biotechnology companies are passionately focused on speeding new medicines to patients who need them. Usually with nothing on the market, they must look externally for funding. When topline trial results are positive and the next phase is imminent, young biotech companies face accelerated – sometimes explosive – growth, which creates an urgent need for the right resources. With a proven scientific rationale for the mechanism of action, multiple propositions for additional indications, an expanding pipeline, and sufficient financial resources, a major bottleneck for necessary organisational growth is the ability to quickly recruit employees with the right expertise, especially in the current competitive marketplace. Then, should there be any significant delays due to scientific, regulatory, or manufacturing issues, biotechs that have ramped-up by hiring scores of people now have a lot of people on their payrolls with little work to do while timelines stretch out to the horizon. Massive hiring, whether doubling a team from four to eight people, or tripling an organisation from 50 to 150, is the 'make' in the 'make vs buy' decision-making process.

On the 'buy' side, an outsourcing model designed to provide dedicated staffing within particular functions offers biotechs the bandwidth, breadth of services, and geographic reach they need, while de-risking heavy payroll expenses, as well as the co-employment risks that come with depending on contractors. By breadth of services, we highlight pre-approval functional services including data management, statistics, medical, supplies, contracts and payments, regulatory, medical writing, quality assurance, monitoring and programme management, as well as post-approval lifecycle management, real-world evidence generation, publications support, medical communications, and on and on. It's important to note that even within the 'make vs buy' discussion, there is no one-size-fits-all solution. There are many considerations that biotechs face when they choose, or have no choice but to go down the 'buy' path.

Common Trajectory and Characteristics

The shared characteristics of successful biotech companies shape the distinctive resource needs they often face. These companies have developed their product from the bench through clinical trials and some keep their assets all the way through registration and marketing. A rapid phase of growth follows proof of scientific concept and initial data confirming hints of efficacy and a reliable safety profile. This opens the door to continued development in the lead indication, investigations for other targets, exploration of additional indications, and the design and development of backup and new compounds.

With the initial proof of efficacy, the risk for investors decreases, while with the variety of targets and indications, the potential value of the company significantly increases, making it easier to attract funds. Such was the case

Case study 1: An urgent need for volume and expertise

Challenge

- European biotech with a large investment working on its first submission
- Needed to ramp up quickly with resources across many functions, working within client culture/systems/standard operating procedures (SOPs)
- Required internal change management support
- Rate-limiting factor: after trying for months with little success to hire upwards of 50 people with the right experience, skills, and cultural fit, the biotech turned to CROs for options

Solution

- Biotech chose internally managed trial model ('insourced') to operationalise most of its trials, with CRO FSP staff providing services and scope where hiring had been ineffective
- Dedicated FTE FSP model for most services with staff based in several countries across Europe and North America
- Services provided for data management, medical writing, regulatory affairs, biostatistics, site contracting, clinical supplies, medical, administration, clinical operations, and programme development lead
- CRO-managed flexible hourly contract resources where needed, which include consultancy services for statistical sciences and CMC

Results

Currently providing ~10% of the total staff, with services ranging from administrative support to medical director and continuing to grow into 2021 with a model that is fully supported by client's functional teams.

for both biotechs in the accompanying case studies, although the first was very close to registration, while the second was earlier in the development process. Nevertheless, with the pipeline and funds aligned, biotechs need to quickly add expertise to actually do the work. It's critical to have skilled resources who have done the work successfully before, as biotechs often don't have the management bandwidth to hire, train, and coordinate employees. Every step closer to submission, and each activity beyond that, is new territory for the company while working toward out-licensing or the initial authorisation and launch.

The main characteristics of these biotech companies and the resulting resource needs are listed in the table (page 38).

Specific Mindset and Culture

The biotech development path is complex, and the ideal functional service provider (FSP) partner must have resources with the skill and flexibility to get up and running quickly, work across studies, and overcome unexpected challenges at any step along the way.

Case study 2: An urgent need for volume and expertise

Challenge

- US-based biotech with a large investment and deep portfolio of investigational products in multiple oncology indications
- After initial focus on adding data management services, needed to ramp up other resources quickly within and outside the US, working within a mix of client and vendor systems/SOPs
- Required internal change management support
- Rate-limiting factor: after trying for months with little success to hire upwards of 30 people with the right experience, skills and cultural fit, the biotech turned to CROs for options

Solution

- Biotech chose the full-service model for trial delivery with two CRO partners, but lacked the staff to manage the CRO vendors
- Dedicated FTE FSP model for data management, clinical operations, site contracting and medical monitoring services, with staff based in several countries across Europe and North America
- Some dedicated FTEs provide oversight services, managing full-service CROs awarded various clinical studies. Important to note here that the FSP vendor parent company is also one of the two full-service CROs. Therefore, FSP-provided managers in some cases oversee their own CRO as full-service vendor. In this case, it is critical for there to be strict firewalls for escalations within the CRO, separating the FSP oversight managers from the full-service CRO team in terms of issue escalations

Results

Globally allocated staff across multiple functions and countries. Client feedback on team integration and solid individual performance has led to a more than doubling of FSP staff allocations over the past two years.

Beyond technical skills and relevant experience, core competencies also include grace under pressure, being proactive, stress resistance, and willingness to contribute actionable ideas for improvement, on top of the more common excellent communication skills and a 'get-it-done-yesterday' ethos. In the midst of a pandemic, it is a given that all resources must be able to excel while working remotely since the new normal may be that workers are no longer required to be in their company office every day.

Another critical point is that FSP partners must understand how extremely important their candidate drugs are to biotech companies – failure often means shuttering doors, and redundancies. It all comes down to partnership and trust because the success of the biotech hinges on the effective execution of an FSP model by staff with the right mindset and competencies.

Five or ten years ago, most FSP models were designed for large pharmaceutical companies. Now there are myriad choices, which makes it necessary to choose the best possible resourcing or outsourcing model for each individual situation.

Once a model is selected, it's time to find an FSP partner who can provide the right expertise in the right locations, including smart, proactive, and flexible people with critical reasoning and decision-making skills. Look for experts with good heads on their shoulders who are up to the challenge of all phases of a biotech development programme. An FSP partner must be able to offer these great staff members at all levels, from administration and operations to global executives, such as medical directors and programme leads, who manage an entire programme from discovery up to and beyond marketing authorisation.

Build for Flexibility, Cost Efficiency, and Risk Reduction

A variety of steps can be put in place to ensure the smoothest flow of resources in the constantly changing biotech world. This includes attention to a process for ad hoc requests and quick ramp-up and ramp-down of staff members. Best practices include:

- **Role mapping** – Working together to outline the descriptions of specific roles, understanding how these map to roles at the FSP partner organisation, and translating that knowledge into a resourcing plan. Where needed, holding an alignment call between functional leads to discuss the specifics of the roles in scope.
- **Forecasting** – Determining where the dynamic environment may result in ad hoc needs, high-level indicative forecasting of needs is critical to anticipate upcoming requests. When biotechs put off planning and find themselves with urgent, yet predictable needs, they then have to settle for the most available people, not the most suitable people. Said another way,

Characteristic	Resource need
Starting company, small to midsize, often local scope	Extensive expertise in key functions such as regulatory strategy, clinical monitoring, or programme development lead
Initial local presence and scope	Global availability ranging from a single, key local resource up to an entire regional or global team
Planning to advance products through the full life cycle	Skilled across every aspect of the drug development process and access to a partner with extensive expertise in all phases of drug development
High-potential development programme that may expand into a regional or global programme	Can help scale up/keep up with growth and explore further potential indications
Large workload and little time for onboarding or training new people	Staff who are 'low maintenance' and seasoned enough to jump in and learn proactively/independently, quickly becoming a seamless part of the team
Growing, dynamic organisation	Staff who can onboard quickly, are flexible, critical thinkers, and can contribute to improvement of processes

instead of getting Mr Right, you get Mr Right Now.
- **Communication** – Ensuring seamless communication between the client and vendor via multiple channels, such as assigned programme leads, dedicated recruitment leads, other supportive functions and close interactions between departmental leads of both organisations.
- **Process** – Establishing clear agreements on each step of the resourcing process from end to end, including timelines.
- **Technology** – Using shared tools to make the forecasting, analysis and requisition process as efficient as possible.

Two Hot Topics: Cost and Risk Reduction

Hiring managers at companies large and small typically think in terms of salaries. Biotechs thinks that if they hire a manager at €/£100,000 a year, then that is their budget. Therefore, if they go to a vendor to get a manager, then perhaps with a 10% or 15% vendor profit, the vendor should charge them €/£115,000.

However, when you hire someone at a €/£100,000 salary, that is not what it costs your company. Your company has to also pay a bonus, perhaps, and taxes, perhaps health insurance and retirement schemes, bank and personal holidays, sick leave, as well as computer equipment, mobile phones, help desk support, perhaps a car allowance, and, in some countries, a lunch allowance. The list goes on and on. Generally speaking, a person with a base salary of €/£100,000 can cost your company €/£250,000-300,000. That's why vendors charge €/£250,000-300,000.

For many years companies, instead, have turned to contingent workers (CWs) in place of direct hiring, hoping to avoid some taxes, benefits, and paid time off. This can be a smart move when you need people part time, for short periods. However, around the world, CWs, employment regulators, works councils, and taxing authorities are cracking down on companies deemed to have violated co-employment and misclassification rules. This has led to back pay and benefits payouts, as well as penalties in the €/£10s of millions. The solution when you need a steady, full-time workforce that gives flexibility from burgeoning payrolls, direct costs, and debt, is working with vendors who are the employers themselves, or, if necessary, manage any CWs on your behalf.

Joint Governance, Teamwork, and Training

Establishing an FSP executive governance structure allows you to bring emerging corporate needs to the surface to be able to pivot quickly as things change. It's often during the governance meeting that specific needs, challenges, or resource constraints come to the surface – issues that can prevent the growing biotech from moving trials forward. Within a productive partnership setting, the joint understanding of these issues leads to the proposal of effective solutions. These solutions may be provided within the agreed FSP model, but the FSP partner also should be able to offer solutions via other agreements (e.g., time and material contracts) if those would be considered to be more suitable.

It's also critically important to create an infrastructure for success, including onboarding and training all resources on standard and evolving processes. Best practice connects an FSP people manager/HR staff member to the client's resourcing or HR team to help with the onboarding process and serve as a resource during the engagement. The agreed performance metrics at the programme level serve to monitor how successful the FSP partner is in managing the programme. In the case of young, fast-growing biotech companies, the right metrics should be selected to measure the quality of the staff assigned, the right fit of the staff provided, and the speed of providing solutions to requests.

Lastly, it proves advantageous to choose a partner whose employees receive strong biotech-specific training. When FSP staff understand the unique needs of biotech companies, they make better recommendations, forge stronger relationships, and more efficiently deliver exactly what clients need.

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