Resourcing Drug Trials Can Be Done in Many Ways. Which One Is Right for You?

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Pharmaceutical and biotechnology companies that operate or manage drug trials face some familiar staffing challenges. As with their counterparts in other industries, these organizations must make strategic decisions according to the needs of the portfolio and the available internal talent in order to find the best solution to ensure success. Where organizations need additional personnel, they have a range of staffing models to best maximize quality, efficiency, flexibility and cost benefit. These include direct hires as well as a variety of options available through working with vendors including staffing agencies and contract research organizations (CROs) as well as independent or contingent workers.

Meeting staffing challenges has traditionally meant either hiring a full-time employee (FTE) or a part-time contractor, depending on forecasted workloads. For pharma companies, however, those two options may be insufficient, leading many to look for alternative resourcing models.

This article outlines the advantages and disadvantages of today's most popular sourcing models as they apply to pharma companies, but these observations have broad application across industries or sectors. When examining each approach, companies should consider how each option supports their need for fast, flexible decision-making and reliable, cost effective execution.

Direct Hires: A Classic for All the Right Reasons

When the demand from unmet workloads can sustain it, sometimes the best option is to hire a new FTE. This can be the simplest path from certain perspectives: The hiring company controls every element, without the need to enter into third-party contracts or assume any co-employment risk. Admittedly, those risks are generally low, but one cannot discount the possibility that the vendor could go under, be bought out, change policies or so on.

The downside, of course, is that FTEs are often the most expensive option once salaries, taxes, benefits and overhead are all accounted for. In the realm of clinical research, as with many other areas, this approach also puts the heaviest burden on the pharma companies' lower and mid-level managers in terms of vetting, on-boarding, training, performance management and career development. Often, operation managers are experts in their clinical trial's field, but they may not excel at (or care to undertake) all the HR-related minutiae that go into hiring and managing new employees-let alone locating and hiring the best new employees.

In reality, hiring a new FTE offers the least flexibility in the face of rapid change, requires the most active management and necessitates the right infrastructure (on-site, remote or even both). This reality drives demand for alternatives.

Independent Contractors: Good Help is Hard to Find

When pharma companies do not wish to take on the risk and burden of an FTE, they may turn to independent and freelance contractors, which often represent the lowest direct cost to the employer. There is no third-party overhead, no benefits, usually no taxes withheld by the pharma company and no unemployment insurance, as these are costs absorbed by the independent contractor.

Perhaps the biggest downside to this approach is that the quality of the talent pool varies widely and it can be difficult to find, interview and engage independent experts with the specific skills required

for any given project. What's more, because the sponsor company is going solo, this model requires a large burden, nearly as much as direct hiring, in terms of administrative, legal, financial and other oversight.

Finally, using contractors in long-term, full-time roles increases the risk of co-employment and false self-employment misclassification, and is facing increasing scrutiny (and fines) from employment and taxing regulators. Corporations have long run afoul of these regulations, with examples ranging from the 1996 case of Vizcaino v. Microsoft Corporation[1] to Uber's recent spate of court appearances.[2] Organizations should avoid using contractors in long-term/full-time engagements and should never adopt this approach as a means of avoiding employment-related costs.

Staffing Agency Contingent Workers: A Good Fit for Short-Term, Part-Time Needs

To solve the problems of finding and vetting independent contractors *de novo*, pharma companies may seek the support of staffing agencies to find and do limited preliminary screening of contractors. One advantage with some of these agencies is the potential to tie multiple contractors to a single contract, simplifying contracting, invoicing and payments. Although the external spend savings may not be as great as with independent contractors, staffing agencies still offer reduced costs–both in terms of lower costs and fees when compared to CROs and lower or absent fees for worker benefits (health care, retirement, unemployment compensation, etc.).

However, just like independent contractors, this option is only suited for short-term, part-time requirements to protect against co-employment and false self-employment risks.

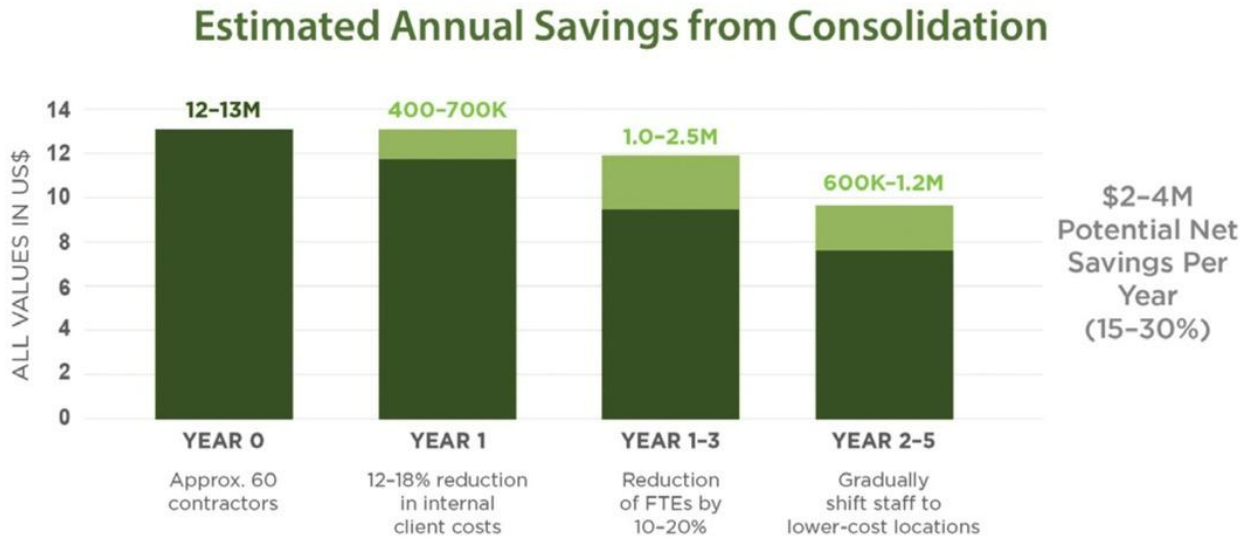
In the best of circumstances, pharma companies benefit by tapping the vendor's database of qualified applicants. However, this is highly dependent on the vendor and its capabilities, so it is out of the hands of the hiring company. When a pharma company makes a good match and desires to do so, it is generally possible to convert that role to a directly hired employee–although fees may apply.

To realize the full range of potential benefits enabled through partnering with contractor agencies, the hiring company must be sure to work with a top-tier provider that is closely aligned with its goals. A slight reduction in costs quickly loses its luster in the face of employees with little or no training, support or oversight–particularly when these and other factors lead to high turnover, which in turns drives expensive hiring, on-boarding and re-training that can jeopardize operational goals and quality.[3] Research by Gallup has shown that highly engaged business units[4] (those that focus on concrete performance management activities, such as clarifying work expectations, getting people what they need to do their work, providing development and promoting positive coworker relationships) improve retention by 24% (in high-turnover organizations) to 69% (in low-turnover organizations).

CRO/FSP Vendors: Full Resourcing With All the Benefits

Among pharma companies looking to avoid painful swings in work volume and therefore in FTE levels, there is need for workers who are neither full-time employees nor part-time contractors. This need gave rise to CROs that support the full-service outsourcing model, where CROs "run" an entire trial or project. It also spurred the development of the functional service partnership (FSP) model, where pharma companies keep the management of research trials and post-marketing support internal ("insourced"), and look to "bolt on" certain functions or services, such as statistics or drug safety surveillance, as the FSP vendor works alongside pharma company staff.

The FSP model is growing in popularity when measured by outsourcing spend, where estimated spend is projected to grow from $18 billion in 2021 to nearly $26 billion by 2025. Under the FSP model, the CRO is responsible for providing the services and experts necessary for their client's needs. The most successful FSP vendors cover most or all functions and services, from pre-clinical and clinical services to marketed products, to provide whatever service or services best fill the gaps in a pharma company's internal capacity or expertise.



One popular capability of FSP models enables the employer to transfer staff off its payroll and onto the payroll of the CRO.[5] The sponsoring employer then re-engages that same staff, but now as contract workers employed by the CRO. Around the industry this is sometimes referred to as "rebadging" or "badge flipping." This model benefits employers and staff alike:

- Staff experiences little or no downtime as they're assured secure employment, either with the sponsoring employer (as a contractor) or via new positions with the FSP CRO.
- Pharma companies gain flexibility, may save money, and certainly benefit from shifting large swaths of human resource expenses from fixed to variable, with no loss of stability as tried-and-true staff continues in the same roles as before without negatively impacting ongoing programs.

As one gauge of the FSP model's potential financial impact, global CRO PPD estimates, based on experience with multiple clients, that a large pharmaceutical sponsor with roughly 60 independent (freelance) study managers across several high-cost locations could see significant benefits. Aside from mitigating the co-employment legal risk, the new FSP model targeted 15-30% annual savings (from the fifth year on).

By covering a wide range of needs and offering a varied portfolio of experts and capabilities, the CRO/FSP model allows for ultimate flexibility. The CRO already has available staff on board (or has a database full of potential staff and per diem experts) to support a pharma company's short- and long-term needs. That means the sponsor can avoid all of the responsibility for selecting, interviewing, background checks and all the necessary onboarding tasks. CRO FSPs, unlike staffing agencies, also offer options such as unit-based and milestone-based contracts. However, much of the workforce in these scenarios are still FTEs, but now as employees of the CRO. Accordingly, the CRO still carries (and the client still covers) the costs of taxes, benefits and overhead, as well as margins.

For pharma companies, FSP vendors offer stable, trained, long-term, flexible solutions with less co-employment risk, and less management and administrative burden, particularly when a single contract covers all research trials or projects supported by the vendor.

Summary: Take Time to Weigh the Options

While this breakdown of hiring practices applies to many roles in many industries, the challenges presented by traditional hiring models are particularly relevant in drug development, where it is especially difficult to fill management roles with high-value workers. These roles require long-term, highly qualified, highly compensated personnel to drive operations across the board–from human trials to approval and marketing. Organizations that run clinical trials and/or have products on the market benefit greatly when they take the time to carefully analyze all hiring options and weigh the pros and cons against their specific day-to-day needs and long-term operational goals. Ultimately, the optimal solution–direct hire, contractor or CRO/FSP–has to secure and retain the best talent while remaining flexible and resilient in the face of rapid change.

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