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Capacity Management Within Functional Service Partnerships

Looking at the advantages and disadvantages of moving capacity management from sponsors to their FSP vendors.

Resource capacity management involves the forecasting and evaluation of resource needs ("people") across a project or portfolio of projects, and the timely allocation of those resources to most efficiently meet project objectives. In any industry, the ability to manage capacity effectively is critically important. The more complex the project or portfolio, the more difficult it can be to make sure resources are correctly forecasted, in place and trained to perform well when needed, and efficiently utilized.

In the pharmaceutical and medical device development industry, as clinical trial protocols have become more complex and involve more outside partners to execute, managing capacity has become equally complex, but remains paramount to the success and timely completion of trial objectives, as well as the financial health of the sponsor. Without solid capacity management, resources can be underutilized, leading to unnecessarily high costs, or overutilized, leading to timeline risks and quality issues. In both cases, there is also a higher potential for resource turnover, either due to staff boredom or staff burnout. This article explores the advantages and disadvantages of moving capacity management from sponsors to their functional service partnerships (FSP) vendors.

BACKGROUND

When a pharma company, biotech, or medical device company ("sponsor") runs a trial internally, it needs to estimate the number, type and location of roles needed, and then evaluate the need for using internal staff, direct hiring and/or contracting with contractors, agencies or clinical research organizations, or CROs ("FSP vendors"). Historically, when sponsors look to partner with an FSP vendor, they simply inform their vendor(s) of their resource needs based on these internal evaluations.

The benefit of managing this process internally is that they retain control of this key element of project execution, staff management and costs. This benefit, however, is often attained at the expense of a significant administrative, financial, legal and oversight burden, and may not be a core competency of a sponsor. Moreover,

importantly, with each sponsor there may be subtle incentives or influences to over- or under-estimate the resources needed.

For example, when the sponsor's clinical operations leaders manage resource forecasting, they may pressure to overestimate resource needs in order to better insure against timeline delays or quality issues, and otherwise maintain corporate milestone targets. When, on the other hand, a sponsor's finance or procurement group is responsible for managing external resourcing, there may be an underestimation of need, with cost considerations weighing more heavily in the decision-making process.

DATA-DRIVEN CAPACITY MANAGEMENT

CROs are driven by competitiveness in the industry to forecast and allocate resources with a high degree of accuracy and efficiency to maintain a pragmatic balance between maximizing utilization, a realistic workload and quality. This is true both in the full-service outsourcing (FSO) model, as well as within a functional service partnership (FSP). And while sponsors long ago ceded capacity management to FSO vendors, such has not been the case with FSP vendors, particularly in full-time equivalency (FTE) FSPs, where vendors provide staff who are 100% dedicated to a single sponsor. In fact, it could be argued that managing capacity is even more important within the FTE FSP space because resourcing within this environment is a singular focus and, as a result, there is more downside to forecasting errors with immediate consequences.

Successful CROs, therefore, have developed systems to analyze protocols, projects and/or scope and specifications using sophisticated algorithms, and to review and refine resource forecasts empirically. The result is more accurate forecasts of what resources are needed, where they are needed, when and for how long. These same tools and algorithms are used whether managing a single project or a portfolio of projects as part of an FSP.

For unit-based FSPs, sponsors generally rely on their FSP vendors to forecast the unit volume need, with the vendor being responsible for completing a task or group of tasks, primary to the specific resources required to complete them. In other words, as long as the FSP vendor staff delivers the units in a timely way with high quality, then sponsors need not be concerned with capacity management.

In contrast, for FSPs based on FTE allocations, where CROs typically provide 100% dedicated, or "ringfenced" staff, sponsors remain resistant to relinquishing this forecasting responsibility. This is due in part to the tradition that staffing is fundamentally a sponsor responsibility, but also a concern that the FSP vendor will overestimate the resource need in order to bring in more revenue. Better FSP vendors should be able to support their resource forecasts and allocations by enabling sponsor visibility into ongoing performance and utilization metrics throughout the life cycle of the project. This way there can be a fluid, collaborative dialogue about resource capacity as the dynamics of the project change or as needs ramp up or down.

Therefore, when FSP vendors support their forecasts with key performance indicators (KPIs) and metrics to analyze and confirm the "right sizing" of projects as well as the high-quality performance of the allocated resources, concerns about over- or under-resourcing can be managed effectively by the sponsors

without the sponsors themselves being forced to manage every hour of every FSP resource.

As capacity analysis and management is by necessity a core competency of any successful FSP vendor, to maximize cost savings and efficiencies, the clinical development industry needs to evolve toward sponsors passing the responsibility of resource management to their FSP partners. If a sponsor with marketed products incorrectly manages resource capacity, there may be a minor impact on profitability. If an FSP vendor gets it wrong, it may go out of business. Our industry is heavily incentivized to manage capacity with the highest level of efficiency in order to balance high performance, cost savings, while promoting job satisfaction and high resource retention for the FSP vendor staff themselves.

Because of the increasing acknowledgement in the industry of CRO proficiency in capacity management during the more than 20 years CROs have been supporting FSPs, there is an increasing number of case studies in which sponsors are delegating capacity management to their FSP vendors, resulting in demonstrable gains in quality and efficiencies through detailed review and scrutiny of current utilization practices, KPIs, thereby generating significant cost savings.

CASE STUDIES

The following are two case studies that exemplify best practices and their benefits and efficiencies.

Case Study 1 – Clinical site monitoring FSP

Sponsor is a top 10 pharma company that was internally managing more than 40 active projects (clinical trials) across 46 countries, using a combination of nearly 700 internal and FSP vendor staff. The FSP vendor staff alone included approximately 60 local study managers, 65 project assistants and more than 300 CRAs, spread across 130 separate vendor contracts. As part of a vendor streamlining effort in 2015, coupled with a move to centralized management model within the sponsor, a single CRO was chosen to provide all clinical operations FSP staff globally. The FSP vendor initiated a collaborative effort to review scope and workload on a project-by-project, country-by-country level to build a stable and integrated FSP workforce while ensuring business continuity for the 40+ active trials, as well as new project starts. As part of this effort there were several joint-team workflows established for ongoing work on different aspects of best practices designed to maximize the effective management of resources.

One workflow focused on a review of protocols and of staff versus site geography to look for monitoring redundancies and/or overlap, and an evaluation of actual utilization of current staff including contractors. A second workflow centered on creating and tracking productivity measures allowing visibility into key performance metrics designed to help monitor project objectives; areas such as monitoring visits (MV) performed within window, MV days on site, MV reports completed on time, data cleaning metrics, etc. This provides the ability not only to target areas of concern operationally, but by having more accurate forecasting of project objectives and deliverables, it also allowed for the ability to effectively and proactively plan resource needs. In this case the team was able to plan forward three to six months, reducing

the average time to fill roles from a global target of 90 days down to almost 50 days, leading to a more stable workforce and better continuity of project operations. A third workflow was created to establish monthly meetings with the sponsor for the review of resource workload. These collaborative reviews provided the opportunity to examine individual project objectives and the resource requirements for those objectives.

The result of these efforts was an overall reduction in resource need and associated cost by approximately 20%. In summary, once capacity management shifted to the FSP vendor, a volume of work that had required roughly 700 people could be conducted with only 450 people, with zero delays and maintaining high-quality KPIs. With a large project like this one, where the sponsor's annual FSP spend can be $50-100 million or more, the bottom-line savings are significant.

Case Study 2 – Post-marketing regulatory affairs product license support FSP

With another top 10 pharma company, this client relied heavily on their own regulatory affairs lifecycle management staff to internally manage and maintain more than 5,000 product licenses across 160 countries around the globe prior to engaging with an FSP vendor starting in 2013. This required an integration of the vendor's regulatory staff expertise and tools with the sponsors' local and global regulatory managers. Joint workstreams were comprised of regulatory experts from both companies, including change management experts from the FSP vendor. The core objective of the joint workstream was to set global KPIs and improve processes and procedures to maximize quality and both time and cost efficiencies.

The workstreams reviewed resource requirements including which specific functions would remain in-house at the sponsor, which would be outsourced and ultimately an evaluation of the effective utilization of the resources across the board, using the vendor's resource forecasting tools. Since then, on a quarterly basis, the scope forecast and required resources are assessed by the vendor and approved by the client. Data from different sources are gathered by the vendor team to assess the workload, including:

- Join team review of upcoming submissions (approximately one to two quarter view);
- Up-to-date regulatory and legal information maintained by the vendor;
- Specific initiatives or scope extension requiring change of processes and/or resources (example: planning for impact of Brexit); and
- Then, the required FSP vendor resources are automatically calculated using vendor forecasting tools.

On a monthly basis, the vendor provides:

- Resources required (Forecasted FTEs);
- Resources used (Actual FTEs);
- Completed submissions and other tasks and deliverables;
- Any significant deviation +/-10% of forecast is analyzed and discussed with the sponsor; and
- Trends for the last six months on workload and resources

forecasted and completed.

It is critical to note here that the FSP contract started out as a unit-based FSP, where there was no guarantee the FSP vendor staff would be 100% dedicated. However, over time, the sponsor chose to restructure the engagement as 100% dedicated FTE-based.

The results of shifting capacity management to the FSP vendor, and the initiation of strategic process reviews and refinements, led to a decrease of approximately 40% in resources needed while simultaneously improving quality and submission timelines. With an overall annual spend for the FSP vendor of approximately $5 million, the corresponding cost savings to the sponsor are again substantial.

These case studies are, of course, examples of very large programs that generated considerable efficiencies and cost savings, in terms of millions of dollars each year. Although this level of success is unlikely to be attained for all FSPs where the vendor manages forecasting and capacity management, the same strategies of customized review and evaluation can be applied to projects of all sizes and with all sponsors.

CONCLUSION

Part of the challenge FSP vendors face in convincing sponsors that they would be better served if they allow the CRO to manage resource capacity is overcoming the traditional mindset that it is, and should be, the sponsors' responsibility to determine resource needs. Many sponsors are simply unaware their FSP partners can provide this high-level capability, in which case it becomes a process of education for the CRO to show by example the effectiveness of its method and the potential impact on the current project being planned.

Also included in the equation should be the understanding that not only does effective capacity management streamline resource utilization and result in more straightforward benefits as described, but it also has a secondary effect, as alluded to earlier, of improving job satisfaction for those who are allocated, leading to increased job retention and better sponsor business continuity. By working through this process collaboratively and transparently with sponsors, it becomes a win-win scenario for both parties—sponsors get cost savings and efficient execution of their project objectives, while FSP vendors can grow their business with an expanding portfolio of sponsors that have benefited from the partnership. CP

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