



How Functional Service Provision can Directly Impact Clinical Trials Success - Crucial Factors to Select the Right Model

It has become quite evident for pharmaceutical companies that their approach to the implementation of a functional service provision (FSP) directly impacts how successful those FSP teams will be. This is why, before any pharmaceutical company makes that decision, it should fully understand how to utilise its CRO or CROs to attain the best possible results with FSP teams. In outlining a modest roadmap, it is important to delve into the challenges when trying to achieve 'sustained' quality.

Sustained quality begins with picking the right model and exploring myriad critical areas to safeguard its success: planning, training, cultural fit, staff retention, technology, communication, agility, sponsor participation, performance indicators, expectations management, etc. It is also helpful to clearly understand the four models (uncapped T&M, capped T&M, fixed fee and ring-fenced FTEs) and the key advantages and disadvantages they bring, based on clinical trial requirements and actual real-life experience.

In doing so, it's important to consider the crucial success factors involved in order to mitigate the risks that can disrupt a clinical trial losing time, effectiveness and potentially damaging the sponsor/vendor relationship. Through the feedback from people who have worked within an FSP team, we have uncovered what works best from the standpoint of those involved operationally.

The first of two main trends in outsourcing is the project-based model. The difficulty with such a model for big pharma that are accustomed to in-house groups is that they typically have a steady stream of questions going to the study teams. This is because they are used to initiating changes and utilising internal resources to address often-changing requirements. Often, when this approach is deployed with a CRO, they run into taking on change orders and then become dissatisfied.

The second trend encompasses managed, full-time equivalent (FTE) pools, otherwise known as functional service provision (FSP). Typically, medium or large companies take interest in these because they quite often have internal teams, but have the need to supplement them for fixed periods, managing peaks and valleys to keep employee overhead down.

The four main delivery models for FSP are as follows:

- **Uncapped time and materials (T&M)** – This often entails using the systems and SOPs of the pharmaceutical company. It can be low-profit work if the CRO does not achieve the correct blend of senior to junior resources, or higher cost regions to low cost regions. However, it is a straightforward delivery model and

agreeing on change orders is less contentious. Price increases tend to be inflation-linked and usually work on a two- or even three-year pricing model.

- **Fixed fee** – Generally performed using the CRO's own systems and SOPs, less commonly using the pharmaceutical company's infrastructure. Pricing can be difficult to get right when delivery is on the pharmaceutical company's systems as it involves processes of which the CRO has no experience at first. Pharmaceutical companies should allow time for learning, followed by efficiency gains over the period of the contract. Fixed fee FSP can include lengthy projects and can be of high complexity. For the CRO, defining the complexity levels during or after the bid process is key to avoid making a financial loss on high-complexity work. This model can cause conflict within the pharmaceutical company – pitching procurement needs against the requirements of the operations department. This potential risk needs active management.

The CRO needs to fit in with both the pharmaceutical company's procurement team and operations team and needs to be strict on working to contract as change orders are difficult to obtain. The CRO is often treated as part of the pharmaceutical company's own delivery team; the FSP manager is therefore key to this relationship and the customer procurement team will expect pushback if their operations team start requesting work outside of contract. The CRO is expected to police the scope to ensure what is delivered is within it, and to ensure change orders are managed up front and prior to work being completed. The pricing of hours required to deliver units has to be correct or the profit margin slips away very quickly. Creating a pricing model that the pharmaceutical company can use before allocating the work will help build confidence and trust; change orders may then be more easily accepted. Fixed fee usually operates on a three-year pricing model.

- **Capped T&M** – This often entails using the systems and SOPs of the pharmaceutical company. The key is to manage caps very carefully using percentage complete versus hours worked. Capped T&M can first appear to be quite profitable for the CRO. The risk is that caps are hit before the work is completed and no change orders have been agreed in advance. The CRO may have to write off hours that cannot be charged. The CRO must review and monitor project performance constantly. It also needs to manage the workload, not take on too much or commit too many employees to the contract as the work can suddenly disappear. This applies to all delivery models. Typically, capped T&M also operates on a three-year pricing model.
- **FTE or ring-fenced** – This is a T&M model, fundamentally, but the pharmaceutical company buys 100% of the resources' time. They, therefore, pay for the resource whether they use

them or not. The pricing is often annual and linked to inflation. The model is again often used working on the pharmaceutical company's systems and SOPs. It is usually low-profit as the pricing is restricted due to the pharmaceutical company comparing the cost to that of contractors or in-house resource, forgetting that the FTE is managed by the CRO. There can be a risk that the CRO cannot ramp up, as the price is too low for the salaries required to recruit the level of staff the customer wants. Staff may be required on customer site at times and the customer will want senior staff as often they expect them to manage/interact with their own employees. Often the work is not complex and this leads to boredom and a high staff turnover.

From real-world experience and feedback from the field, we have come to realise just how important it is to anticipate the risks of each model and assurance of measures to be implemented to ensure sustainable quality, customer satisfaction and staff retention.

Building Long-term Relationships

For CROs there are a few critical success factors to consider to reach a long-term sponsor/vendor relationship. The vendor needs to guarantee 'sustained' quality. It is not acceptable to deliver ten good people (who are perhaps more expensive) and then, in an effort to get to a target margin, reduce the quality of the next ten by buying in cheaper resources and repeat that again with the next ten. Any plan needs to deliver an agreed margin, which may be lower than the vendor wants but will unlock more work in the medium/long term. The CRO needs to conduct ongoing pre-selection of candidates to avoid rushing and recruiting sub-optimal resource.

Culture Assessment

The cultural fit between the pharmaceutical company and individuals in the FSP team is important. The pharmaceutical company must be able to screen to ensure there is a cultural fit with the person and not just technical suitability. Character profiling is often overlooked in the heat to meet demand. It is important that individuals can work to the values of the pharmaceutical company.

Getting the pharmaceutical company involved to some extent in the CRO's HR processes can be beneficial in aligning expectations and building trust with the selected CRO.

Communication and Transparency

Communication and transparency are crucial. Therefore, if KPIs can be agreed in the area of communication, both parties can agree on their expectations. Typically, the team will be located in different offices and different countries. This can be acceptable to a pharmaceutical company in the knowledge that they may get the necessary blend of high/low cost with some team leads that are local to their own for regular communication. For example, the mix could be 40% high cost, 20% medium, 40% low, and the geographical spread may enable the appointment of more experienced resource in each country. Time zone is important to achieve essential day-to-day communications to get the work done.

Technology and Effective Training

Technology-wise, it is often most efficient for the CRO team to access the pharmaceutical company's technology environment remotely and work within it. One person or a small group can be trained directly by the sponsor who, in turn, can train others as needed. This is known as the "Train the Trainer" model. The CRO should deploy internal management to monitor quality and productivity. KPIs should be monitored in this respect and shared with the pharmaceutical company at regular governance meetings. The FSP manager at any given location is critical to the relationship. Typically, the pharmaceutical company and vendor can agree on a ratio of one FSP manager to a particular number of resources.

Retaining the Team

Team attrition can be a big factor in achieving an ongoing quality service. If the team is located in an unattractive location, attrition can be higher. In addition, the team lead plays an important role in keeping individuals motivated and happy in their place of work. Salary is, of course, a key factor, so if the CRO has agreed to a five-year price deal that is unsustainable due to demand and salary increases for a particular skill set, then attrition only increases as





employees are lured to higher-paid positions in other companies. Sponsors have often found that CROs who are good at delivering fixed fee projects are not good at delivering FSP and vice versa. FSP is a very different mind-set and modus operandi. Sponsors and vendors need to be aware of this if trying out FSP for the first time. Oftentimes it works best where the sponsor supplies the team leads and the CRO employees are treated as an extension of the sponsor's own in-house team.

Agility and Scalability

An important factor in evaluating a vendor is to see some evidence of their ability to ramp up to meet the pharmaceutical company's work plan. A typical question is how many resources does the CRO have in the particular functional area. The answer may be a high or a low number, but whatever the case, it does not bear any relation to the number of resources available to the sponsor. No CRO has idle staff in great numbers, so the sponsor has to expect a ramp-up period. The CRO needs to have a credible ramp-up plan, preferably with some previous track record of success. It should be transparent to the sponsor how many resources will be existing employees and how many will be recruited.

Experience and Expertise

Having testimonials is helpful to support a bid. The bid documents themselves need to be very well defined, and fully aligned with the needs of the pharmaceutical company in terms of timescale, skill levels, pricing, workload and communication.

Competitive Pricing

On the subject of pricing, a blend of low-cost resources with medium-/high-cost ones ensures a competitive overall price, but it is important to build in inflation if the pricing is to last more than a year. If the bid is via an online reverse auction,

robust models will need to be built to quickly calculate margin at different prices. The downside of this procurement method is the significant risk to sustainable quality if the price is driven too low. It can become impossible to recruit the right level of resource so the vendor fails and the sponsor is left with an urgent problem to solve, to avoid pushing out study end dates.

In Summary

Overall, sponsors who already have experience with FSP should evaluate what aspects are working and which are not, as there may be a better model available. They should also make sure that the contract details are going to be sustainable for the CRO because they will ultimately be affected by resource constraints or team turnover. CROs need to evaluate if they can really meet the experience levels, resource numbers and pricing sought by the sponsor. A realistic ramp-up plan should be agreed between both parties to align expectations.

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