

More than 'Rent a Body'

Are CROs a necessary evil or should partnership be the watchword?

Pharmaceutical outsourcing of clinical development to traditional contract research organizations (CRO) has grown steadily through the 1980's and 1990's. CROs have established their role in filling manpower shortages, relieving pressure on drug sponsor staff and expanding into new geographical areas and therapeutic fields. Yet there remains much dissatisfaction with the transaction on both sides. Why is this?

In the past, big pharmaceutical companies treated CROs with caution, using them rather as an ad hoc extension of their own clinical development departments – 'hiring pairs of hands'. Typical reasons cited for and against outsourcing are shown in Table 1. The attitude overall could be described as seeing CROs as a necessary evil. In many ways the CROs themselves exacerbated this situation by merely presenting themselves as extensions of internal development departments and by accepting competition based on cost alone. This has led to a perception of low value being attached to CROs work and low status conferred upon their staff.

Problems common within the sponsor-CRO relationship have included the rent-a-body mentality; lack of breadth and depth of experience within the CRO; unsophisticated choice and management of contacts by the sponsor and real or perceived failure to deliver by the CRO. These factors have led to sponsors seeing their role as controlling the CRO by setting constraints on its ability to go off and do what it does best – manage clinical trials. There has been a tendency to micromanage the CRO against the context of these constraints leaving little room for manoeuvre in how the CRO delivers, while at the same time insisting that it bears all the responsibility. In turn, CROs have been too accepting of time and cost constraints which often the sponsor would not be happy to accept, instead

of wresting more control over how the contract is implemented. At best this leads to a failure to deliver against the client's expectations and at worst can take the CRO into financial difficulty.

The commonly told stories of CRO underperformance are a natural outcome of this form of relationship made worse by the relative lack of good sponsor internal benchmarks that help the contracting officer develop realistic budgets and timelines with their CRO. Often when presenting a proposal to a pharmaceutical audience there are always those who disbelieve the figures and insist their company or department is markedly better. It is no surprise that when dealing with a CRO these same individuals insist upon unrealistic time and cost based goals that they themselves could not meet. Disappointment ensues leading to the third major problem of 'serial shopping', where the sponsor works with one CRO, perceives unsatisfactory performance, chooses a different CRO for the next contract and so on until even-

tually coming back to the first CRO convinced that outsourcing is a complete waste of time.

Many pharmaceutical sponsors have recognized the difficulties and have responded by reducing the contracting process to a mechanical one, often relying on body counts rather than achievements, numbers rather than thought. This amounts to a lose-lose situation that is often enhanced by the contracting officer's lack of involvement in the delivered product. For this reason the best contracts are between a sponsor and CRO who thoroughly understand clinical development and have a stake in the outcome.

CROs must take some of the blame for past difficulties. Growth in volume of business has been the strategic intent of many, yet such growth brings challenges in maintaining quality and customer service. This has led to variable performance effectively masked by slick marketing efforts. How many times have you been very impressed with the CROs business development depart-

1. TYPICAL REASONS FOR & AGAINST OUTSOURCING

FOR	AGAINST
To staff development departments to the 'valleys' and not 'the peaks'	Lack of contact with opinion leaders
Lack of in-house expertise	Lack of contact with future prescribers (investigators)
Speed up regulatory submission	Perceived lack of commitment of CRO
Better access to; <ul style="list-style-type: none"> • investigators • therapeutic expertise 	Difficult to access study databases <ul style="list-style-type: none"> • patients • technology
Help with investigator recruitment	Loss of in-house experience
Reduced overheads	Perceived high cost
Gains in quality and reduced development time	Uncertain stability of CROs <ul style="list-style-type: none"> • Staff turnover • Maintenance of infrastructure • Financial
Global regulatory capability	Lack of openness about pricing, capability
Developing multiple indications in parallel	Lack of sponsor contracting expertise

ment only to see it replaced by a relatively inexperienced project management team once the contract is signed?

A better, more sophisticated approach to outsourcing is beginning to emerge driven by the fact that the modern pharmaceutical company is faced with a single pressing issue – how to generate sufficient revenues from marketed products to sustain its development pipeline and thus future revenue growth? Additionally, that pipeline grows larger each year, a situation set to intensify as new candidates emerge from scientific advances such as combinatorial chemistry and genomics. Thus far, the industry response has been to achieve even more mass through merger and acquisition. But whilst recent mega-mergers receive much attention none has, at least to date, achieved a genuine increase in productivity or boosted the number of successful drugs brought to the market. The choke point continues to be clinical evaluation with all its complex, intensive and slow moving processes and increasing regulatory demands. Every pharmaceutical sponsor needs to systematically examine the efficiency of its internal development process and accept that a significant move to increased and more effective outsourcing must occur - a lesson learnt and put into successful practice by other industries.

For many industries outsourcing is old hat. The three top reasons, apart from reduced cost, commonly cited for going 'extramural' are, 1) improved company focus, 2) access to world-class capabilities, and 3) freeing up resources for other purposes. Companies in other industry sectors have learnt the principles of effective outsourcing and the burden of proof has shifted from "Why outsource?" to "Why do it here?"

For example, the American car manufacturers sat fat and happy until the late 1970's when they were faced with competition from the Japanese who had (among other approaches) a team-work relationship with their contractors that enabled effective pooling of expertise – and sharing in the rewards that improved the product. The pharmaceutical industry is facing such a shakeout in the future, one that will be driven by smaller, and nimble development companies that can draw on the expertise of team members and work more effectively in reaching a common goal. This will be facilitated through

2. TEN TIPS FOR SUCCESSFUL OUTSOURCING

- ACCEPT YOU NEED EACH OTHER - BOTH PARTIES CONTRIBUTE VALUE
- ENSURE THERE IS BOTH SHORT AND LONG TERM STRATEGIC 'FIT'
- DEVELOP SHARED WAYS OF WORKING TOGETHER
- INCULCATE A FEELING OF JOINT OWNERSHIP OF THE PROJECT
- UNDERSTAND EACH OTHERS CAPABILITIES AND PLAY TO THE STRENGTHS
- INVEST IN EACH OTHER
- UTILISE ELECTRONIC MEDIA FOR COMMUNICATION AND SHARING OF INFORMATION
- MOVE THE BUYER-SELLER RELATIONSHIP FROM THREAT TO COMMITMENT AND COLLABORATION
- AVOID CONFLICT BY MANAGING TRADE OFFS (THERE ARE PLENTY IN CLINICAL PROJECTS!)
- BEHAVE WITH INTEGRITY. THIS DEVELOPS MUTUAL TRUST.

electronic tools that are just becoming available, although most of the current products largely only scratch the surface of potential that this electronic medium offers.

Today, both CROs and sponsors are re-evaluating their relationship and setting it in a new context of partnership (Table 2). The sponsor is expecting the CRO to bring something more to the table than just extra hands to turn the crank. Equally, the CRO expects the sponsor to take advantage of and trust in its people, knowledge, and technologies rather than trying to limit them.

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The electronic tools now becoming available should facilitate this transition. Such tools mean that data collected from a site can be cleaned and entered into a database within a couple of days and then made readily accessible to the project team drawn from both CRO and sponsor.

The electronic medium presents new opportunities to improve transparency of study performance and facilitate communication and understanding between sponsor, CRO and even regulatory authorities. Recent examples exist where a sponsor has contracted simultaneously with several different CROs on the same program or study, taking the expertise from each and molding it into a team of complementary skills. Such an approach encourages more openness and interdependencies in delivering the objectives and has resulted in a far greater sense of ownership amongst the participating

CROs. Furthermore, these sponsors encourage and reward the CRO for expanding its expertise and developing new and better approaches that benefit the project in hand. Sponsors and CROs will become more aligned in the future, sharing the risk and upside of clinical development. Some commentators see an expansion into preferred partner relationships that benefit the larger, globally integrated CROs at the expense of smaller service providers.

However, these relationships only prosper so long as excellent performance is maintained and there will remain a role for smaller CROs who possess a competitive advantage in one or more of the clinical development processes e.g. electronic data capture or site management. This will leave the sponsor as manager of the outsourced team - setting strategic objectives, then helping the team deliver. Control of the process can be achieved through innovative use of electronic media and by performance-based contracts with sufficient carrot as well as stick to motivate and drive CRO performance. Such risk sharing contracts are now becoming more popular though there is still a tendency for sponsors to be reluctant about the carrot and CROs to fudge the stick.

Successful outsourcing can consistently be achieved by developing a relationship between sponsor and CRO based on mutual respect and trust, plus a clear understanding of what can and cannot be achieved. Only by moving the construct from 'rent-a-body' to partnership can the true benefits of reduced cost, accelerated clinical development and better quality be achieved.

THE AUTHOR

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