

Outsourcing Clinical Trials

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Commercial pressures are driving pharmaceutical companies to look for new, smarter ways of working. The pressure to maintain share prices has resulted in strategies to triple the number of new products reaching the consumer.

In the late 1980's, R&D budgets typically ran at 10% of sales, now they are approaching 20%; equating to an annual spend in excess of \$39 billion. Nearly a third of this budget, \$12 billion, is being spent with clinical research organisations (CROs) in an attempt to increase throughput, resource the workload peaks and gain increased market share through faster times to market.

During the last five years many CROs have seen turnover increase 20-30% year on year, as pharmaceutical companies have sought to outsource an even wider range of services. Clinical studies are also getting larger, more complex and many require CROs to have a global operation.

Discord

Unhappily, this increasing trend towards outsourcing has not brought all the anticipated benefits, as there is often conflict between the two parties. What starts out being branded as a partnership soon dissolves into an unhappy relationship between customer and supplier, driven only by inappropriate service level agreement terms. Unclear definitions of responsibility, poor communication and a failure to understand the needs of the other party are leading to dissatisfaction for both sides.

A recent study by Center Watch determined that the rate of effectiveness of pharmaceuticals working with CROs is running at less than 40%. While pharmaceuticals complain that CROs overextend their staff and overestimate their abilities yet fail to understand their special needs, frequently leading to promises that they cannot keep; the CROs respond with their own set of complaints. These include an inability to understand how to work with a vendor, no clear consensus on objectives for the trial as well as poorly documented needs and outdated, inadequate systems plus, of course, they never commit enough resources to the project. Clearly, in order to meet the targets set for the future, the relationship between these two parties has to improve, and manageable sets of working practices established.

New Technologies

By 2005, the industry expects that more than half of its target compound will be derived from new technologies, such as genomics, proteomics and bioinformatics. A high profile death last year as a direct result of genomic therapy has raised major concerns about the safety of these therapies and the need for well controlled clinical trials including the requirement for stringent screening of candidates to assess their suitability for inclusion in any trial. Managing these new environments and their associated challenges is going to be hard enough for the pharmaceutical companies, but to try and attempt it in partnership with an organisation that is not in harmony, will be extremely risky – for both the reputations of the pharmaceutical company, the CRO and the patients.



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With the dramatic increase in the number of clinical trials, there is an even greater demand for suitable participating patients, who are now rapidly becoming a scarce resource. In addition, the number of patients required to be involved in any clinical trial has doubled in the last ten years. In order to protect their interest, the investigators, who are in effect the customers of the process between the pharmaceutical companies and the clinical research organisations, are forming site management organisations (SMOs). As SMOs have ultimate control over the enrolment of suitable patients, their position and importance in the clinical trial process has increased adding extra complexity into the dynamics of the inter-relationships making it more difficult to manage effectively.

Data Management

More trials, more patients ultimately lead to more data being generated, and this is clearly demonstrated by the delay in the industry between patient visits and submission of the data to the authorities. The average delay is approximately 850 days. Given that in the pharmaceutical industry the value of bringing a product to market one day earlier is estimated at being \$1 million, the cost of this delayed data is certainly expensive. Any gains in cleaning, processing and presenting clinical trial data would be significant in both commercial and financial terms. The lack of standard processes and computer systems within the industry to collect and manage this data is adding to the problem.

Selective Outsourcing

In many other industries 15-30% cost savings have been achieved through the successful use of selective outsourcing. In addition, 50% improvements in both cycle times and quality are also being reached, with strategic relationships being formed. If outsourcing can work for other industries, what does the pharmaceutical industry need to do to make it work for them?

One of the major reasons for failure is that although the benefits of outsourcing in terms of lower costs, increased operational efficiency, better data and shorter time to market are understood, many pharmaceutical companies have no comprehension of the CRO market, the cost implications to them, both financial and time, and no cohesive outsourcing strategy. The result is a short-term relationship that benefits neither party.

Steps to Successful Outsourcing

From its considerable experience with outsourcing strategies across a range of industries, WCI has developed a three-phase approach and then tailored it specifically to address the individual needs of the pharmaceutical industry. The first phase is purely about understanding the strategic fit of CROs within the organisation, the CRO market and the cost implications, while developing the internal tools approach that will help manage the relationship. In the second phase, the goals and processes are aligned to make the process more efficient and effective before moving into the third phase of managing an ongoing seamless relationship.



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Develop a Cost Model

An increasing workload, time to market and a requirement to increase productivity, rather than an opportunity to reduce costs, has often been the driver for outsourcing within the pharmaceutical industry. However, there is a growing awareness of the potential for cost reduction, but many companies do not have a cost model that helps them to understand what the true costs of all the activities in a clinical trial should be. Conversely, the CROs have a good grasp of their cost base and what constitutes profitability which gives them a significant advantage when negotiating contracts. Unless a pharmaceutical has a baseline of actual costs against which to compare quotations from CROs, they are at the mercy of the level of competitiveness existing between their contract bidders. The cost model also supports the decision making process.

Hence, the development of a simple and easy to use base level costing model is essential. Most pharmaceuticals have already developed a task matrix that reflects the activities involved in a clinical trial, adding an extra field or two containing the cost drivers and associated cost for these activities is all that is needed to produce a tool that will have a key input into the overall outsourcing strategy.

Integrated Outsourcing Tool

The outsourcing tool provides the basis for all discussions between the pharmaceutical and the clinical research organisation from agreement to the completion of the clinical trial. It also enables the pharmaceutical to measure the performance of the contract against its set objectives, and to clearly see the overall effect of any change in any one of the main objectives. The outsourcing tool integrates the cost model with project planning and with the measurement of the timeliness and quality of delivery of the clinical trial.

CRO Market Analysis

Although information about CROs and trends within their industry are easily available, in both the public domain and from specialist companies who track and trade this information, it is also important that the pharmaceuticals collate and analyse their past experiences with each CRO. This requires an objective analysis of the performance of the CRO, together with an understanding of how good a culture fit there is between the two companies. For this analysis to have credibility and buy-in at the right levels, all the key players across all geographic areas must be included. This analysis will identify a short list of potential CROs, from which the pharmaceutical will select its final long-term partners.

Make Outsourcing Strategic

Outsourcing has to become a strategic part of the business, and it is important that the strategy is developed with co-operation from the final implementers of the strategy. Using the cost model and the CRO market analysis, the pharmaceutical has to make decisions that will optimise the benefits to itself from outsourcing part of its work to a CRO. A clear action plan on how to implement the strategy must be drawn up, but subject to continual revision according to the changing needs of the business and market forces.



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Aligning Goals

Traditionally the selection process has been one where the CRO talks about its skills and ability to deliver. By absorbing this phase into the market analysis phase, pharmaceuticals now have the opportunity to offer CROs the challenge of making their case on how they can contribute to the successful implementation of the outsourcing strategy and what value creation they expect both sides to see out of the partnership. This forces the discussions up a gear, and makes each side consider the longer term impact on the potential relationship, helping to remove some of the barriers to success at the outset.

This is the CROs opportunity to commit to working with the pharmaceutical to achieve mutual goals and have an input into optimising the effectiveness of the process for both parties by agreeing on best practices.

To ensure the success of the relationship, the selection of CRO partners must be made with the agreement of all key players across all geographic areas.

Aligning Processes

Only once a relationship has been established and working practices are in operation is it possible to move into a process alignment phase. This is an opportunity for process transformation optimising the efficiencies – doing it the right way – to be established. The outsourcing tool again comes into its own as the mechanism for analysing the results, tracking the changes and measuring the associated reductions in cost and increases in efficiency.

Often it is in the areas of collecting, cleaning and analysing the data that great opportunities exist for improvement with speed of collection and increased accuracy in the data sets being two key areas.

Just creating a process where both the pharmaceutical company and the CRO can view the same data instantaneously results in shorter decision times about the success or failure of the clinical trial. Major costs benefits can be achieved simply by being able to 'retire' a project that is not achieving its objectives quickly.

Building Long Term Relationships

Only when all these other elements are in place and working across all levels within both organisations can the two parties move into the creation of a strategic relationship. Try to do it earlier, without all the rest of the processes and understanding, and it will fail. At this point the boundaries of the two companies blend, their goals become common ones and they not only manage the process of the clinical studies together but also are pro-active in creating the future. The success of each company becomes ingrained in the other and they both act for mutual benefit exploiting their core competencies and realising all the anticipated rewards that a true outsourcing partnership can deliver.



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