SCRIP MAGAZINE
September 2003
Pharmaceutical Issues in Perspective

Paying for the pitch

Phase II and III clinical trials cost millions of dollars, yet CROs are still expected to produce tenders at their own cost, while pharma relies largely on arbitrary selection criteria. But, ask Dr Michael Bowden and Steve Mackenzie-Lawrie, is industry paying too high a price for free proposals?

An aeroplane manufacturer, when outsourcing the construction of a wing, hardly expects the contractor to submit a proposal that merely indicates the general shape, construction material, approximate weight, and a vague hope that it will stay attached to the airframe in flight. Instead, the manufacturer sets out precise time, cost and quality objectives and the contractor is expected to provide a proposal that delineates construction right down to the last rivet. This can be called a 'project-defining' proposal.

A pharma company, on the other hand, could – based on some current practices – award a clinical trials contract to a CRO on the basis of a proposal that has had to be developed and written with a minimum of time for planning, and with limited information, background research and feasibility testing. Assumptions will often have been made on the study's duration, patient populations and location of sites. This means the costs involved in the management and execution of the study are usually estimates, with a susceptibility to 'budget creep' and the potential for future budgetary disputes regarding costs and fees. Ultimately, both parties may have unrealistic expectations of timelines, costs and quality once a study commences.

Unless money is invested in clinical trial proposals, too many assumptions and guesses must be made, usually based on past performance metrics which may well have changed

Free, but at what cost?

Yet examples of good competitive tendering processes are not hard to find. They have been regarded as an essential part of outsourcing contracts for many years in the automotive, aerospace, defence, construction and governmental arenas and this experience could be utilised in the pharmaceutical industry. Pharma generally expects that contractors will provide proposals at no cost to the sponsor. In other words, proposals are regarded as a cost of doing business and an investment by the CRO. Could this be why there is such a huge variation in the quality and content of proposals submitted in the pitch process? Could it be why sponsors find outsourcing such a challenge to manage effectively? And why too many trials overrun both in duration and cost?

In order to address these questions, pharma could follow the example of the automotive, aerospace and other industries in the adoption of a more efficient competitive tendering process linked to proposal fees. Such fees would be paid for those genuine project-defining proposals of the small number of CROs that reach the latter stages of the tendering process.

With many of the problems related to outsourcing clinical trials being a direct result of insufficient time spent in the competitive tendering process itself and the lack of drive to expect and produce project-defining proposals, there is undoubtedly a case to be made for 'paying for the pitch'.

Certainly, the current set-up creates vast potential for errors and inaccuracies in several areas. Firstly, inadequate objectives may be handed to the CRO within a traditional request for proposal (RFP). While it can sometimes be difficult to define specifications accurately in clinical trial design, expectations should be clearly made for the common elements such as trial duration, patient enrolment rates, investigator site identification, quality metrics and costs.

Secondly, proposals can cost CROs a significant amount of money, even when written to their current standard. A typical proposal may consume 10-15 days of staff time, especially if short feasibility studies are conducted. Anecdotal evidence indicates that CROs may spend US$30,000 or more to produce a Phase III clinical trial proposal. Many CROs are reluctant to invest this amount of money unless a clear, transparent competitive tendering process is in place. Yet without this kind of investment, too many assumptions and guesses are made, usually based on past performance metrics which may well have changed. This can lead to inaccurate assessments of timelines and costs that only come to light once the clinical trial commences. Alternatively, those CROs that do consistently produce expensive project-defining proposals fear all their hard work and intellectual capital may merely be passed on to the sponsor and/or its selected CRO 'free-of-charge'.

Even if only some of these common problems apply, then an unfavourable environment currently exists that is directly leading to costly delays in clinical trials.

Effective tendering

A competitive tendering process can be divided into four key stages: a request for information (RFI) sent out to a number of contractors; qualification and evaluation of potential contractors chosen from the RFIs received; formulation of the written tender material and an invitation to tender (the RFP); and final selection of the contractor and formulation of the contract.

This may be a familiar outline to some, but there are essential principles which need to be adopted for the process to work:

- Initially, the client should seek a variety of contractors, not just those from a particular sector or size. It is important to inject variety and the opportunity to seek different detailed value propositions later in the process.
- Neutrality must be achieved. Qualification and evaluation should not be marred by lack of objectivity or past favouritism. The competition must be conducted, and be seen to be conducted, in a fair and transparent manner.
- No more than three CROs should progress to the RFP stage. This is important in the context of focusing on the true value being proposed and in whether proposal fees should be paid.
- The sponsor must be clear about its expectations and the deliverables required from the CRO.
- Over-specification in the RFP should be avoided to the extent that it impedes the

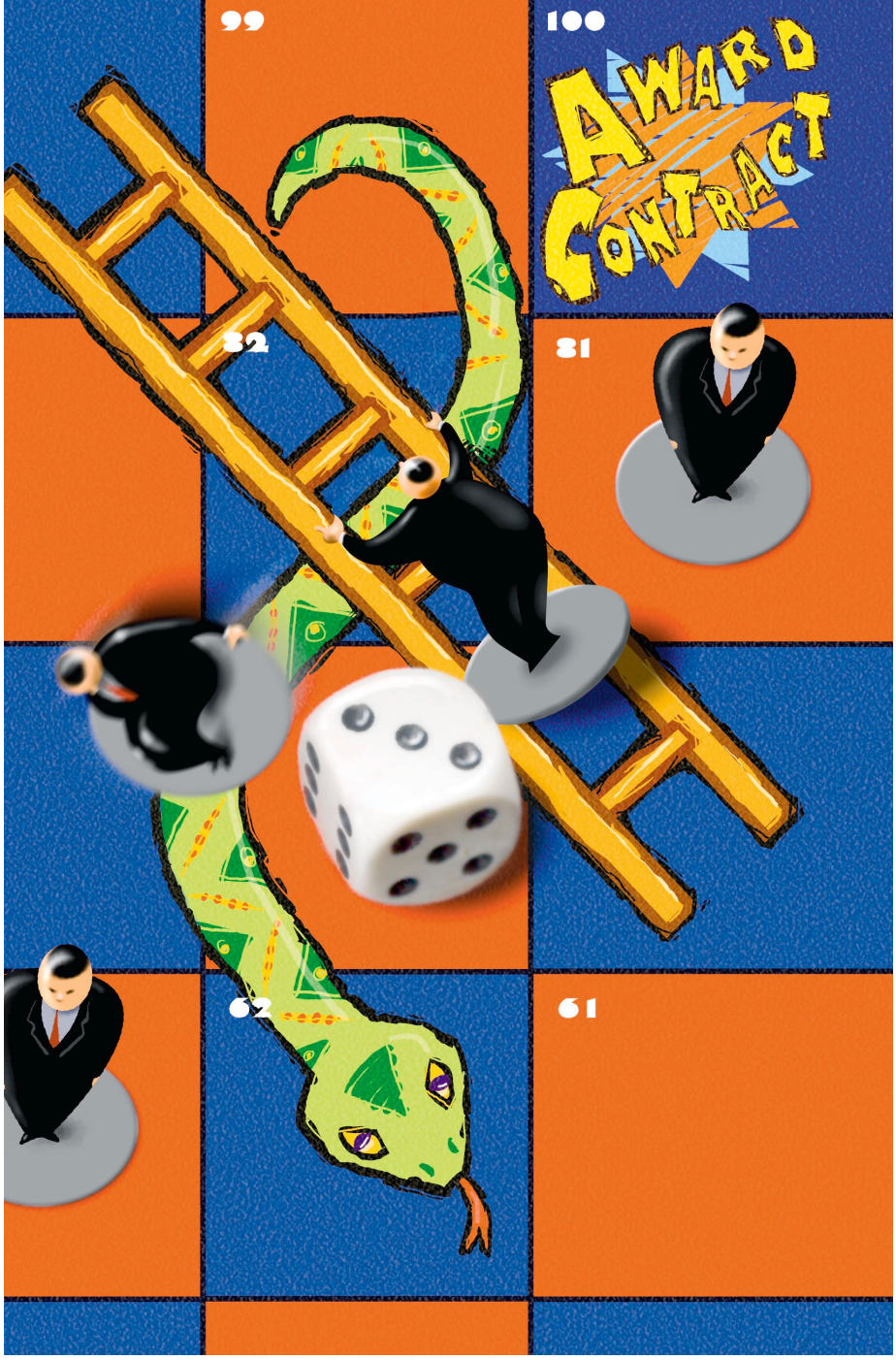

Illustration by Rob Wilcockson

Who wins and who loses in the contract tendering process is very much a game of chance.

CRO's ability to rationalise its operations with maintained or increased deliverables.

There are substantial advantages to adopting a more effective competitive tendering process. Firstly, a clearly defined clinical trial is obtained at the outset, with risk and uncertainty reduced for both the CRO and the client. Secondly, more innovative solutions can be sought and provided by the CRO and thirdly, time and cost overruns are minimised once the clinical trial has started. Experience has shown that project-defining proposals allow approximately 75% of clinical trials to be successfully completed either on or ahead of time.

The high cost of tendering by CROs is not the only factor to take into consideration. A CRO may have to wait up to 12 months to find out if it has been successful in securing a contract, leaving it with the problem of ring-fencing the people and resources originally identified in a proposal. This cost of uncertainty is immeasurable, and is of course multiplied by the numerous competitive tendering processes in which a CRO participates.

Something for nothing?

But why should the industry care? To answer this, it is worth asking where current practices lead.

Any service business forced to adopt increased risk must adjust its costs to allow for this. In fact, the only incentive for a CRO to produce higher quality proposals is the competition with other CROs. On its own, this incentive is clearly failing to produce the timely and cost-effective clinical trials we should expect. In addition, a general lack of both transparency and neutrality in the tendering process puts a break on innovative thinking and a solutions-driven approach to conducting clinical trials, because the benefit of that effort may simply pass to a competitor. Above all, the real objective of reducing clinical development cycle time is compromised.

Actual costs are difficult to quantify because there are two components – the additional costs of having resources dedicated to trials that take longer, and the lost opportunities from delays to market, which will vary from product to product. But the figures are hardly trivial and can probably be measured in billions of dollars across the industry. Perhaps the best measure of delay-to-market costs is that development cycle time has not changed in the past decade, despite many initiatives supposedly driving R&D efficiency.

So if pharma adopts the solution of a more effective tendering process linked to payment for proposals, what could be considered a suitable fee to 'pay for the pitch'?

Based on CRO costs, it would seem that a proposal fee of 1-2% of the contract price is a realistic aim. Although the initial cost to a pharma company would be higher, this would be reduced by limiting the number of CROs reaching the final stages and by a contractual agreement for the proposal fee to be reimbursed against the contract fee. Proposal fees should only be paid for Phase II-III clinical trials where timely execution to predictable cost and quality are more critical than in early phase or post-registration trials.

Above all, proposal fees would offer an incentive for CROs to design project-defining proposals that will ultimately save pharma a great deal of money – avoiding longer clinical trial programmes and delayed times to market. Indeed, producing project-defining proposals can be seen as being in the best long term interests of a CRO as well as the pharma company, since it can only improve clinical trial execution and hence the relationship with pharma sponsors.

This article will doubtless be read with thought in some quarters and scepticism in others. But in an increasingly difficult environment for pharmaceutical clinical trials, the time is right for sponsors to invest in the pitch process, in terms of time, information and money. The result will be a better competitive tendering process and a clear improvement in the quality of proposals. Or do we want to continue with a process where we constantly risk the 'wings' falling off our clinical trials? SM

•Dr Michael W Bowden is managing director and Steve Mackenzie-Lawrie the sales and marketing director of international contract research organisation Health Decisions, based in the UK and the US.

