a full-service CRO to assist with the successful development and execution of their program. Although most CROs do not provide the capabilities for full partnership, a few have demonstrated that they can successfully develop a drug product from inception to clinical proof-of-concept.

Timing/Cost Considerations

Outsourcing becomes attractive, even to those companies who have in-house resources, when these resources are committed to different projects. Timing and costs are two major considerations that come into play when a pharmaceutical company decides to outsource.

Timing is a major consideration for many projects. Although most Phase I studies are not a critical path to an new drug application (NDA) submission, there are times that BA data are necessary to design a Phase II or III study. Occasionally, a BE study, comparing the Phase III formulation with the final marketed product, becomes rate limiting for an NDA submission. At these times, outsourcing is necessary and cost effective because approval (and marketing) delays can be quite costly when compared to lost revenue.

Generic BE studies are often on very tight timelines because the company's objective is to file an abbreviated NDA (ANDA) within 3 to 4 months of manufacturing the clinical lot. The goal of most generics is to be the first to market because the first generic approval provides that manufacturer with a higher profit margin. Each additional approval increases competition and decreases prices (eroding margins). Timing is even more critical when a generic manufacturer intends to file an ANDA with a Paragraph IV patent certification. The first generic to file (as a paragraph IV) is entitled to 6 months of exclusivity (i.e., no generic competition). Six months of exclusivity (for branded or generic products) provides a substantial financial incentive to the pharmaceutical firm. Therefore, because it is critical that the BE trial be completed expeditiously, these companies approach CROs to provide dedicated resources that can meet the company's timeline.

For those studies where timing is not critical, many companies evaluate cost as a basis for outsourcing. These companies will send a request for proposal (RFP) to a number of CROs. The CROs, in turn, will provide study quotations that detail the price for the services. Interestingly, many companies will compare internal costs versus the cost to outsource. However, this comparison often includes only "out-of-pocket" costs (internal salaries) and does not include overhead expenses (benefits, offices, computers, training, etc.).

It is important to compare "apples to apples" when comparing costs/prices (both internal and external). Companies comparing internal costs should utilize all costs (not just salaries). When comparing bids from multiple CROs, it is also important to assess both the prices and deliverables from each CRO. An RFP that is not clearly written may yield a number of proposals with a wide range of prices. It is important for each CRO to identify the assumptions and deliverables behind each proposal. Firms may be disappointed with the end results if they select a CRO based on price alone.