Will CROs Take on the Risks of Strategic Outsourcing?

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It's not clear whether contract service providers can deliver the performance improvements and cost savings that drug companies expect from large, long-term, semi-exclusive contracts.

Do CROs and contract manufacturers really have what it takes to become strategic outsourcing partners? This issue was debated during the Institute for International Research's “Partnerships with CROs” conference in April, and traditional contract services providers seem reluctant to step up to the plate.

The opening session spotlighted the year-old arrangement between Wyeth (Madison, NJ) and IT outsourcing giant Accenture (New York, NY), by which Wyeth gave its entire clinical data management (CDM) operation to Accenture. The company received a 10-year contract to provide CDM services for Wyeth R&D worldwide and acquired 175 Wyeth employees and much of its CDM infrastructure. In addition, it agreed to meet highly specific performance criteria that will escalate during the contract's life. The arrangement grew out of a comprehensive reengineering of Wyeth's clinical R&D operations which is directed by Christopher Gallen, MD, PhD, vice-president and chief of clinical operations and supported by an Accenture consulting team led by partner David Boath. This reengineering effort has already achieved substantial performance improvements at Wyeth R&D, including a three-fold increase in investigational new drug filings, improved clinical performance of pipeline products, and substantial cost reductions.

Gallen had to demonstrate first-year benefits to generate buy-in from corporate and clinical operations managers, Accenture took a loss on the first year of the contract. In future years, much of Accenture's revenue from the deal will depend on the achievement of specific performance targets, many of which will require Accenture team members to manage their Wyeth counterparts and ensure that all parties meet the performance targets.

Although the agreement is somewhat groundbreaking for the pharmaceutical industry, the Wyeth CDM venture is nothing new for Accenture, a $12-billion public company that is involved in many IT outsourcing deals. Accenture has the experience to assess the requirements and risks in large IT programs, and the staff to manage it. It also has an existing infrastructure that the company can leverage (e.g., its service delivery center in India to which it has consolidated data entry from clinical report forms). Finally, Accenture's size—10–20 times the size of the largest clinical CROs—enables it to absorb some initial losses without imperiling its financial performance.

Still, CRO executives who appeared on a panel following the Wyeth–Accenture presentation seemed reluctant to accept that these truly strategic outsourcing arrangements will require them to take some performance risk. The panel members, including James A. Bannon, PharmD, corporate senior vice-president and president of late-stage clinical services at Covance Inc. (Princeton, NJ), and John Climax, PhD, executive chairman of Icon Clinical Research (North Wales, PA), said in response to direct questions that they were not in business to lose money, and that their public shareholders would not stand for losses.

The unwillingness of contract service providers to stand behind their performance is shortsighted, especially when many of them are eager to accept the risks of equity or royalty participation in their clients’ products. It seems that CROs and contract manufacturers have become too comfortable in their role as supply-
Outsourcing Outlook

mental capacity suppliers, which doesn't require them to deliver superior performance and has enabled them to work under the umbrella of high costs that major pharmaceutical companies have established.

CRO executives must be aware that the pharmaceutical industry is undergoing profound changes that will give a competitive advantage to companies that improve operating performance and reduce costs. Led by companies such as Wyeth, that train has already left the station, and the contract service providers better get on board.

**Strong demand for early development services**

Revenue for the contract services industry grew ~13% for the January-March quarter, but preclinical, Phase I, and bioanalytical and laboratory services revenues jumped more than 20% at many companies. Industry executives pointed to increased spending by both Big Pharma and small pharmaceutical-biotechnology companies as a reason for the activity growth.

In fact, capacity shortages may be emerging for preclinical and Phase I services. Aside from taking advantage of the situation to raise prices, most CROs are adding capacity, either through expansions of existing facilities or through acquisitions.

Performance of Phase II-IV services at most CROs was much less robust because of the low level of new contract signings in 2003. According to many industry observers, Phase IIIb (testing for additional indications) and Phase IV studies (marketing and pharmacovigilance) are in the strongest demand. Nevertheless, CRO executives indicated that the flow of new RFPs and contract signings was strong.

In fact, clinical and preclinical CRO executives are so upbeat about the demand for outsourced development services that many companies raised their 2004 revenue and profitability projections. The optimism reflects both the increase in study volume and a firming of the pricing environment. CROs have commanded price increases for preclinical work and have said that pricing for Phase II-IV services stabilized after some intense price competition late last year.

Chemistry services providers still can't share the euphoria of their preclinical and clinical counterparts. Overall, capacity usage is low and competition by Asian companies is getting more intense. Process development service providers are relying on improved financing for small pharmaceutical-biotechnology companies to drive more business their way, but Big Pharma seems more willing than ever to explore options in Asia. As a result of the decline in the demand for discovery chemistry services, Albany Molecular Research Inc. (Albany, NY) has announced a corporate restructuring.