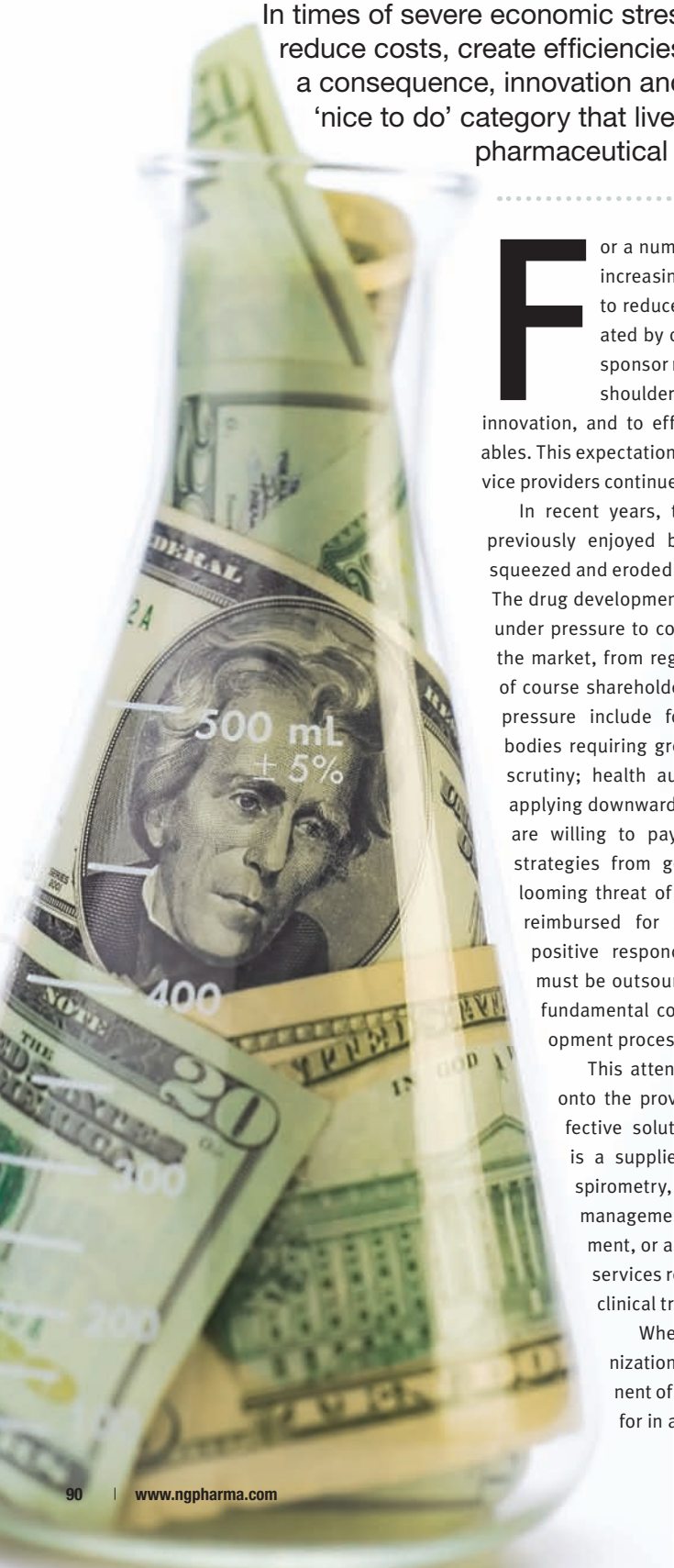
Taking responsibility for innovation

In times of severe economic stress, all sectors of all industries will be seeking to reduce costs, create efficiencies, and generally find ways to ride out the storm. As a consequence, innovation and market development will often be relegated to the 'nice to do' category that lives at the back of the collective corporate mind. The pharmaceutical industry is no exception.



For a number of years, there has been increasing pressure on the industry to reduce costs, especially those created by outsourcing. Increasingly the sponsor needs to rely on the vendor to shoulder the responsibility for service innovation, and to efficiently provide the deliverables. This expectation can only increase as the service providers continue to mature and consolidate.

In recent years, the margins that had been previously enjoyed by the industry have been squeezed and eroded from a number of directions. The drug development organization is continually under pressure to control its own spending from the market, from regulatory bodies, payers, and of course shareholders. The main drivers of this pressure include for example the regulatory bodies requiring greater due diligence and self scrutiny; health authorities and other payers applying downward pressure on the prices they are willing to pay; aggressive market entry strategies from generic companies, and the looming threat of drug companies only being reimbursed for successful treatments, i.e. positive responders. Chief amongst these must be outsourcing costs, a necessary and fundamental component of the drug development process.

This attention is turning the spotlight onto the providers to offer more cost effective solutions. Whether the provider is a supplier centralized ECG services, spirometry, central laboratory, data management, recruitment, site management, or any one of the myriad of other services required to plan and execute a clinical trial.

When a drug development organization looks to outsource a component of a clinical trial, what they look for in a vendor is largely dependent on what their own internal resources have available; or more importantly don't have available. Everybody wants flexibility, but nobody wants the inherent difficulties that come with it; trial leaders dislike the rigidity of a well established process when it does not provide what they need, but like to sleep easy at night knowing that their trial is in a safe pair of hands that use tried and tested procedures. The incongruities of these needs are at the heart of the challenges.

Collaborations

The era of true partnership between sponsor and provider is drawing to a close; it is debatable whether, in the pragmatic working environment, it ever really existed. There were, without doubt, a few laudable examples of success, which of course provided benefits to each party. But alas, on the whole, the majority of relationships rarely stuttered beyond that of the client and the vendor.

The central laboratory providers, who have a more focused offering, will often struggle to secure large long-term contracts against the full service providers. A 30 site phase II study in five countries limited to North America and Europe is a very different animal to a 300 site phase III in 30 countries.

Sponsors rightly have a concern of risk, especially for those with limited pipelines. Similarly, those with plenty to outsource often labor under the misunderstanding that the smaller phase II studies are the right ones with which to pilot a new provider. It could be argued, these are often the most complex, most demanding studies for a provider to manage and execute, and may only prime the relationship for an early failure. To place work with a vendor who has performed

very well on the phase II, but may have limited capacity to deal with the phase III, the risk of failure is just too high.

Capacity in this context is not limited to the number of samples they are able to receive in a day, or the level of project and data management they are able to provide. These are a given. Capacity must, out of necessity, also include the value added services that will shoulder some of the burden of managing a large complex global trial, and give the trial leader that good night's sleep. In these circumstances the full service provider should have the advantage, however it may be that vendors who are able to collaborate and innovate, and deliver this service without risk, will prevail.

Cost

Cost is always a driving factor, and the budget for a central laboratory service usually consists of three broad categories, laboratory testing, shipping and logistics, and the management services. Each of these, to one extent or another, would likely benefit from some innovative thinking that could either reduce the cost or increase the value for spend ratio.

There is an understandable desire to move laboratory tests that have to date been considered of high technical complexity and therefore high revenue earners, into the more routine and commodity driven areas of operation. This will of course always happen, as part of the natural evolution of a laboratory test. However it does also need to be driven somewhat by the market. But it is questionable whether it should be the process of conducting a clinical trial, which does this, or the need for cost effective patient care. Maybe they are just different aspects of the same goal? But nonetheless, the pressure is there, and central laboratories must wrestle with the challenge of delivering these tests in a more cost effective manner.

The cost of shipping these samples to the laboratory continues to perplex many of the trial leaders and managers, and more often than not, is the major contributing factor to an exceeded budget. It is obviously possible to significantly reduce costs by using an integrated carrier as opposed to a premium courier. But in making this decision, the trial leader will need to wrestle whether the reduced cost is worth the elevated risk. This is a case where it is not just the providers who have a key role in reducing costs, but the entire supply chain. Whether it is an innovation in service, pricing, or the business model, this is an area that is certain to evolve in the near future.

Model differentiation

The central laboratory market is competitive; those providers that are already operating in the field are looking for ways to differentiate themselves from one another. On the whole, the core product data is similar from one laboratory to another, and the mechanisms of achieving that are also very similar. Likewise the challenges are similar, and for global providers, the business model will usually fall into one of three categories; the global network of affiliated laboratories, the network of wholly owned laboratories, and the core laboratories where samples are shipped to a limited number of owned facilities.

Of course the reality is that current vendors actually offer a combination of all three to one extent or another. The current trend appears to be moving away from the alliances of affiliate laboratories towards that of wholly owned facilities. The unanswered question remains: will the chosen model give anyone a real market edge? The key to any of these models succeeding is the mechanism by which they are managed, the added value, the ease by which the product, data, can be delivered.

Convoluted and complex internal mechanisms often create challenges for the sponsor, and it is these kinds of challenges they can do without; they just want it to work. The provider and their collaborators, who can make this easy and are transparent in their processes, may find themselves at an advantage.

As we speed towards the second decade of the 21st century, the onus is on the providers to collaborate together in order to offer better products, improved services and greater cost efficiencies for their clients, which are, after all, very often the one and the same. ■

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