

STRATEGIC VS. TRANSACTIONAL PARTNERSHIPS BETWEEN PHARMA AND CROS: ONE SIZE DOESN'T FIT ALL

Despite some recent encouraging momentum, investments into Pharma R&D have been on the decline. The Pharmaceutical Research and Manufacturers of America (PhRMA) noted a drop of 0.3% in its members' spending on R&D¹, to just under \$49 billion, in 2012. 2013 didn't look much different either. It is unclear how 2014 will shape up, but 10-15% spending surges that were not too uncommon in the 1990s are clearly the things of the past.

While no one can predict whether the decline in Pharma R&D spending has plateaued and if the rebound is on the horizon, everyone agrees that the use and reliance on clinical outsourcing vendors is here to stay. According to Agilent's Economist Unit², the predominant number of Pharma executives expects a continued increase in the use of CRO services. The reason for why CROs, both large and small, have been getting more business is two-fold: strict mandate from Pharma's top management to contain costs and lack of internal efficiency and/or expertise to design and execute today's ever more complex clinical trial programs.

The ideal model for the most congruent relationship between Pharma and service providers continues to be the source of debates. Both proponents and opponents of "strategic" and "transactional" relationships are far from reaching the consensus as to which can better address the challenges that Pharma R&D currently face.

Who works with whom?

According to Avoca group³, 70% of large Pharma spends most of its outsourcing dollars with the 5 largest CROs while 70% of small and mid-size Pharma spends only 10% of its resources with the same providers.

A recent Centerwatch survey showed that about 70% of the revenue generated by large CROs comes from strategic alliances with big Pharma where smaller CROs generate more than 60% of its revenue by way of transactional alliances.

These statistics are hardly surprising. It is only large Pharma that can entice a CRO with sufficient work flow to expect certain concessions and it is only large CRO that can provide the breadth of services needed for a truly strategic partnership.

R&D Costs and the types of CROs: correlation or causation?

It is believed that small and medium size biopharma is leaner and arrives at the results faster and with lesser expenditures. PharmaExec analyzed Pharma R&D costs by putting companies into cohorts based on its size and demonstrated that the cost per NDA is directly proportional to company's size, with top 20 pharma spending 90% more than the bottom 100 does.

¹ <http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf>

² <http://www.chem.agilent.com/Library/whitepaper/Public/EIU%20REPORT%20FINAL%20PDF.pdf>

³ <http://www.slideshare.net/AvocaGroup/the-state-of-clinical-outsourcing>

While indirect comparison of the two aforementioned data sets doesn't bear statistical significance, it at least raises an interesting observation.

If smaller Pharma and biotech accomplishes more with transactional relationships and reaches milestones at a fraction of the cost of big Pharma, then there must be some merit to taking a closer look at project-specific interactions.

Best Case Scenario

All Pharma executives want to do good work and to save the company's money without compromising quality of clinical development.

Thus, when faced with the choice between working with a regional or a niche vendor who, in their eyes, requires a heightened level of oversight versus working with a global CRO that promises to take all their troubles away and allow for a rather hands-off experience, most Pharma managers choose the latter. Does this mean that settling for the same partner time after time brings the same good results? Probably not, but it is convenient and does add a sense of comfort, regardless of how elusive it may be.

Nonetheless, niche and regional CROs have a great deal to offer. Firstly, and especially with larger projects and sponsors, they universally bring their "A-team" to the table. As they lack the bureaucracy layers of large CROs, which can sometimes outshine those of the big Pharma, smaller CROs are often able to initiate the study much faster. They usually have better local expertise and more accurately anticipate the potential roadblocks and bottlenecks that large transnational providers may overlook. And lastly, even after all of the "strategic" discounts, smaller, transactional partners remain to be significantly less costly.

Thus, the answers to the question of what type of provider is better maybe an unexpected one. Introducing a smaller, regional but well-validated vendor into a large international trial that is for the most part is managed by a strategic partner CRO has a lot of advantages. In such a combination approach smaller CRO is the underdog that is determined to beat its competitor's recruitment timelines and to excel at every aspect of trial conduct. This often translates into a healthy competition with an established strategic partner CRO, which, if left alone, may be feeling a little too comfortable. So, next time when designing and planning a 20-country, 5-continent pivotal trial, one may want to think of inviting a "transactional" partner to cover a certain country or a geographic region, while granting the bulk of the study to a preferred "strategic" provider. The results of this arrangement may bring a pleasant surprise.