IPI Interviews Dr Chitra Lele

The Chief Scientific Officer at Sciformix Corporation

PEER REVIEWED

R&D Outsourcing and Strategic Parnerships

A recent report found that strategic partnerships with CROs and FSPs create a more integrated approach to clinical development and reduce pharma's level of oversight, decrease fixed costs and provide access to capabilities not found internally.

Q: How have these partnerships evolved and what changes should we expect?

In the areas of clinical development and product life-cycle management, several large pharmaceutical companies have recently defined (or in some cases, redefined) their outsourcing strategies, and have entered into long-term strategic relationships with a few chosen vendors. Organisations that did this a few years ago may need to refine their approach based on their experiences with their vendors. Some companies are realising that they don't have the required level of expertise internally to provide adequate oversight to the outsourced work, so core competencies are being redefined. Some small to medium-sized companies may look for an "optimal" hybrid model of partnering with full-service CROs and FSPs.

Q: How important will these partnerships be in the coming years and what will be the focus?

Such collaborations will certainly increase and existing ones will have to become more impactful in order to address the continuing R&D productivity pressures. These collaborations help the sponsor organisations to redirect their internal focus to the more meaningful business areas and allow the non-core activities to be delivered by companies who specialise in these, hence providing a win-win situation. Going ahead, these collaborations will focus on operational efficiency gains. Emphasis on process improvements, LEAN methodology and automation will drive many of these collaborative processes.

Moreover, pharmaceutical companies are looking for increased sophistication in terms of domain and therapeutic area (TA) expertise from their partners in view of their strategic focus on certain TAs and the increased complexities of the drug development programmes, as well as the increasing number of biologicals. Hence, striking the balance between providing such expertise and also delivering operational efficiencies will be the most significant challenge for all stakeholders in 2014. This will also shape the collaboration approach in terms of the mix of CROs and FSPs (BPOs, KPOs, SPOs).

GLOBAL Outsourcing

According to PwC, global healthcare spending is projected to increase to more than $7.5 trillion in 2020 from $5 trillion in 2010. Spending in Brazil, Russia, India, and China (BRIC) and other non-traditional economies is expected to drive most of the growth. Services, both clinical and non-clinical, will account for an estimated 30% to 45% of spending in 2020, creating opportunities for US providers to expand their brands and generate alternative revenue streams.

Q: How do you think this will impact pharma companies' business models, and what type of global partnerships will be needed in this environment?

Looking into the healthcare and life science sector, we have already started seeing the impact of the shift towards emerging economies. We are seeing an increase, for example, in the number of clinical trials we support for registration in the emerging markets. We have seen an interest in getting more clinical development services, both for the emerging markets as well as for the traditional markets, from countries in the emerging geographies. One of the prominent countries is India, which has seen a substantial growth in the outsourcing of pharmacovigilance and biometrics services.

We have also seen growth in interest to partner for product launch support and medical information services in the emerging markets.

Another impact of this increased focus on the emerging markets is the need to collect more post-marketing data from these regions and to analyse epidemiological and comparative effectiveness data from these geographies. This is very likely to be achieved through partnerships with global services providers with presence in these regions.

Q: Are there any niche areas for which outsourcing vendors can help pharma companies fill a gap in their businesses needs?

A noteworthy area is that of regulatory strategy and affairs at the macro level and specifically, product label maintenance at the micro level. Regulations are evolving in both mature and emerging regions, and hence local knowledge and access to in-depth regulatory expertise drives the sponsor organisations to partnerships which provide these skills. The specific activity of labelling updates and maintenance has increased the workload and hence the opportunity to streamline and automate the task. Therefore, we have seen a visible increase of partnerships in this area.

Q: What trends do you see in the post-approval space?

Post-approval phase of a product is gaining importance. There is a need and an opportunity to collect and analyse large amounts of safety and efficacy/effectiveness data after the regulatory approval of a product. This is an emerging area of substantial collaborations across all stakeholders. The pharma companies will adopt an integrated approach to meet this requirement by partnering with payers, healthcare providers, KOLs and trusted outsourcing partners.

Pharmacovigilance or product vigilance (PV) is currently in transition, with new sources of medical information and methods for its analysis being explored to transform the current

reactive system into proactive benefit-risk management fully adapted to modern technology and needs. PV needs to change from being reactive to regulatory compliance concerns to being proactive as a concerted effort across all stakeholders, closely aligned with actual public health promotion. Outsourcing strategies and partnerships which promote this movement are evolving.

Q: What role does technology play in this movement?

The impact of new technologies in healthcare delivery will create significant challenges and opportunities for all stakeholders in the pharmaceutical industry. One of the challenges is in developing tools for accurate qualitative and quantitative assessment of risks as well as benefits. Improving both the quality of data sources and the tools that are used to analyse the data is key to unleashing this new model. Modern information technologies such as data-mining tools have evolved significantly and allow for enhanced identification of rare, medically important adverse drug reactions.

An example can be seen in the area of signal detection. New models like the Likelihood Ratio Test-based (LRT) method are being developed by organisations like the FDA. Tools and value-added services based on these methods can help pharmaceutical companies realise superior, efficient signal detection, when combined with expert medical reviewer capabilities. This provides biopharmaceutical companies with robust and reliable analysis of adverse event data from clinical trials, as well as from spontaneous post-marketing reports.

Chitra Lele is Chief Scientific Officer at Sciformix Corporation with over 20 years of experience in the healthcare industry. She has been part of the company's leadership from its inception and has been instrumental in establishing and growing the organisation. Prior to Sciformix, Chitra was Executive Director responsible for Indian operations of Pfizer Global R&D. With a PhD in Statistics from Stanford University, her prior experience includes work as a biostatistician in cancer epidemiology at both Stanford and University of California.

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