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Outsourcing strategy for drug development in Asia

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The conventional view of contract research organizations (CROs) bears little relationship with the way in which they were perceived ten years ago. Traditionally, the CROs provided support to pharmaceutical and biotechnology industries in the form of research services on a contract basis. The advantage for the drug sponsor was that they did not have to maintain staff as they moved new drugs or devices from conception to marketing approval.

In 2010, the pharmaceutical sector had the dubious honor of topping all others when it came to job losses. In a single year, pharmaceutical companies cut approximately 54,000 jobs in the US alone and another 28,000 jobs disappeared from the healthcare sector. After this, strategy planning in addition to biometrics, laboratory studies and clinical trials too had to be outsourced.

The large global CROs have matured from their traditional role as body shops for resources and service providers to become specialists in clinical development. Their activities cover all phases of development, data management and study design expertise. As market pressures dictate an accelerated development process, timetables must be reduced with no room for wasted studies. These goals can only be achieved when the pharma and the biotech industries partner with the CROs early in the development process and engage in collaborations rather than employing CROs as though they were hewers of wood and bearers of water.

Sponsors may of course transfer any of their trial-related duties to a CRO, but the ultimate responsibility for quality and integrity of trial data remains with the sponsor. The sponsor ensures that the CRO has on board quality assurance and quality control. Accordingly, the selection of a CRO partner is critical to the ultimate success of any outsourced strategy.

There are currently 1,100 CROs in the world, the size of the market having exceeded $24 billion in 2010. While the revenues are growing year-by-year, the number of CROs is likely to shrink, largely as a result of a continued trend towards consolidation. They range in size from large international full-service organizations with over 20,000 employees, to niche specialty groups, providing clinical trial services to universities and research bodies, government organizations such as

National Institute of Health and traditional sponsors from the private sector.

The pharmaceutical giants have long recognized that up to 70 percent of studies fail to recruit to target and 30 percent of sites fail to recruit a single patient. The CROs have the ability to improve this unfortunate situation by engaging the sites in a collaborative effort, having a genuine global footprint and integrating recruitment and retention delivery systems. In the partnership between a CRO and a sponsor, the latter pays a fee for service and, in an ideal situation, the partnership agrees upon risk-sharing milestones. Once the partnership is established, clinical trial performance improvement leads to reduced time in drug development and optimized analysis of trial results. However, unless the fundamental strategy is right and has taken into consideration regional imperatives, the added value of time-saving is lost. This is especially true in Asia, where the opportunity is matched by the complexity of an ever-evolving regulatory and infrastructure landscape.

A fundamental goal of QuintilesAsia Strategic Drug Development Unit is to work with sponsors to map out a strategic plan that has the end game in mind not simply moving from phase to phase of the trial process but truly understanding the regulatory and market-entry barriers that need to be met once the end zone is reached. This type of strategic planning wraps a safety net around the clinical trial time-line, so that the sponsor can be assured that the time spent in each phase will not be wasted.

In the 1990s, clinical trials were performed in Asia merely because of access to patients. In the last decade, the commercial opportunities of entering Asia markets with global products were recognized. Currently, there is a trend for reverse innovation in which Asian disease trends and medical needs can guide global R&D planning. Asia, however, is different from North America and Europe; it has no unifying FDA or EMEA. The regulatory landscape in Asia is complex. China, Japan, East Asia and the ASEAN countries all have regulatory bodies that differ as widely as their languages, ethnic differences, disease trends and cultures. A strategic plan that works well for the US and Canada may be inappropriate for Taiwan, Korea and Japan. Without Asia-focused regulatory and clinical strategic expertise, physically located in the Asia Pacific region, it is unlikely that globalization of Asian healthcare solutions will occur as quickly as the partners aspire to.

Activities within Asian drug development over the next few years will be interesting to observe. One would predict that the CROs with Asian aspirations will adjust their hiring priorities. Rather than doers of operational tasks, they will focus on the thinkers with vision, Asian cultural sensitivity and ability to plan strategically.

Ten years ago, it was unthinkable that a CRO would have a department of strategic planning focusing solely on Asia. Today, it is a reality.

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