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Fight between local and global CROs intensifies

03 September 2012 | Influencers | By BioSpectrum Bureau

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Mr Malcolm Burgess relocated to Hong Kong in 2011 to take up the role of executive vice president of ICON with special responsibility for the growth and development in Asia Pacific (APA C). Since relocation, Dr Burgess has played a key role in acquisitions and alliances across Asia Pacific as well as the organic growth of ICON's service provision and headcount across the region.

Prior to moving to Asia Pacific, he was responsible for the global clinical research strategy and focused on establishing alliances and partnerships with two major clinical research organizations (CROs) in China and Japan. Before that, he was the chief operating officer for the US clinical research division with additional global leadership roles in biometrics and interactive voice response system.

In addition to his global experience in drug discovery and development, Dr Burgess has also played an active role in establishing off-shore support organizations for both pharmaceutical companies and CROs. He was instrumental in the establishment of a statistics and programming unit in Mumbai, India, in 2000 for Novartis, and more recently, he established two multi-discipline offices in Chennai and Trivandrum.

In an interview with *BioSpectrum*, Mr Burgess shares his views on the CRO industry trends in India and China and the shape it is expected to take in the future.

What have been the trends in the CRO industry in India and China during the last five years?

Global CROs have rapidly expanded their scale and services in emerging markets during the past few years. This has led to a significant increase in the number of global clinical trials in China and India.

Mergers, acquisitions and alliances have become a trend in the CRO industry and the Indian and Chinese markets too have experienced this trend. Many global and local CROs have merged or formed alliances with small- to-medium sized CROs to enhance capabilities and improve local therapeutic expertise. This allows them to better compete for global clinical development programs. For example, ICON acquired BeijingWits at the start of 2012 and this has strengthened our presence and service capabilities in China to better support our clients' requirements.

In the past, the CRO industry focused on monitoring in India. However, this has been expanded to provide a full spectrum of services at different stages of drug development, including project management, medical affairs, regulatory affairs, quality assurance, data management and statistical analysis. This trend has brought large-scale outsourcing business to the country, particularly in the area of data management and statistical analysis driven by advanced information technology and data collection capabilities.

Earlier, Chinese pharmaceutical companies conducted majority of their research within China because local CROs provided a cost-competitive option. However, with the desire to reach a global market, international CROs have become an attractive option over the past few years. For example, Chinese company Tasly Pharmaceuticals appointed ICON to conduct the company's global phase III trials for T89 (Dantonic), which is a botanical product for the treatment of chronic stable angina pectoris due to coronary heart disease.

How do you see the growth of local CROs in Asia?

The pharmaceutical industry is constantly seeking new ways to drive down drug development costs. There appears to be opportunities for local CROs in Asia to grow, while the market is sensitive to price. The local CROs are able to provide a more cost-competitive option to compare with global CROs.

However, they must continue to distinguish themselves as leaders in their areas of specialty through high quality services. As the desire to expand outside their own country of origin grows, more and more emphasis will be placed on the ability of CROs to perform regional studies and ultimately studies that fit the requirements for global drug registration. This will require local CROs to expand their geographic reach or form alliances with the larger regional or global suppliers

More and more global CROs have already formed regional alliance with local CROs to strengthen their capabilities and presence in the countries. In addition, we believe that local CROs bring a real benefit to global CROs, with local knowledge of the market that can be invaluable. For example, local industry experts who have extensive relations with the Chinese SFDA and other local regulatory bodies are helpful in managing clinical trials in a more effective and efficient manner.

It is likely that these alliances, while beneficial to both parties in the short term, will form the basis for future mergers and acquisitions in order to meet the growing client needs for local know-how and global reach. However, there will always be a need for some niche providers who specialize in executing local registration studies in a very cost-effective manner.

What are the challenges in reaching out to the APA C markets?

The regulatory timelines can be a challenge, even though some respective governments are taking proactive measures to improve the regulatory landscape. For a CRO that knows what the challenges will be and how to minimize the hurdles, there are still huge benefits to be had in terms of patient availability. Patient recruitment is still the number one cause of clinical development delays. However, this is not unique to this region and judicious appointment of well-trained investigators can minimize or eliminate these potential delays.

What have been ICON's major developments in the APAC?

Currently, we have over 1,400 staff based in 13 countries across the region and we continue to evaluate our footprint in different parts of Asia Pacific driven by client requirements.

ICON recently extended this footprint with the acquisition of BeijingWits in China which adds significantly to the company's

leadership, scale and service offering in Asia Pacific.

ICON has developed close relationships with a broad network of patient recruitment vendors which also allows it to define the optimal strategy for all studies and together with online GCP and protocol training through Firecrest, ensures that all investigators and site staff are fully trained and confident to meet rigorous recruitment targets. ICON has also improved its performance in terms of quality of data, timelines and transparency through ICONIK to help drive maximum efficiency and ensure studies are on track and proactively managed to reduce risk.

ICONIK enables real-time review of data, drill-down to explore data and proactively address issues and analysis of site quality metrics and clinical endpoints. This in turn enhances clinical decision making, permits validated adaptive monitoring processes, and drives quality and efficiency throughout the study. But most importantly it helps us to focus on risk management and operational effectiveness rather than spending so much time on resolving problems that can be avoided by better planning and risk management.

What are the disease-related focus areas for ICON in Asia?

ICON provides outsourcing of clinical development across all therapeutic areas in Asia Pacific. Oncology is currently ICON's fastest-growing therapeutic area in Asia Pacific, with 167 on-going studies at more than 700 sites. The indications mainly include breast, lung, lymphoma/leukemia, gastric, melanoma/myeloma, prostate and solid tumor. We also have extensive experience in conducting clinical trials within disease areas, including cardiovascular, infectious diseases, central nervous system, endocrinology, gastroenterology and hematology across the entire region.

The prevalence of certain diseases in Asia Pacific makes it attractive for patient access in specific therapeutic areas but these can vary from country to country. For example, diabetes is one of these diseases. Our in-depth expertise in this area enables us to deliver excellence in the management of clinical development programmes and we have strong relationships with investigator sites that ensure high rates of patient enrolment and retention.