BioSpectrum the business of Bio & Health Sciences

New vistas for CROs

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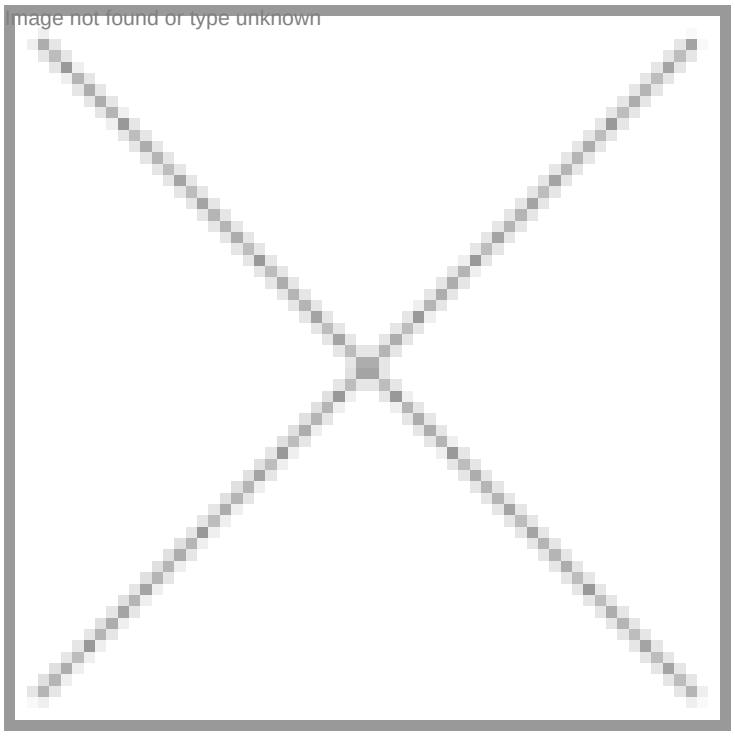

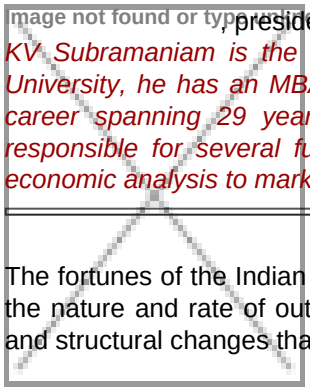

, president and CEO, Reliance Life Sciences, Maharashtra

KV Subramaniam is the President and CEO of Reliance Life Sciences. A chemical engineering graduate from Madras University, he has an MBA from the Indian Institute of Management, Ahmedabad, and a Chartered Financial Analyst. In a career spanning 29 years with the Reliance Group and Indian Petrochemicals Corporation, Subramaniam has been responsible for several functions – from corporate business development, corporate planning, project management and economic analysis to marketing; in a wide range of businesses

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The fortunes of the Indian clinical research organizations (CROs) depend on the global CRO industry, which is dependent on the nature and rate of outsourcing by the global pharmaceutical industry that has been undergoing several domain-specific and structural changes that are creating both opportunities and challenges for CROs.

Events such as the economic downturn, pharma mega-mergers and the US healthcare reforms initiatives, have forced stakeholders, especially pharmaceutical companies, to re-align their strategy towards increasing focus on bio-therapeutics as a product class, and producing more safe and cost-effective medicines. This essentially means that CROs having specialized offerings in their repertoire, and the capability to address a broad range of product and therapeutic classes would be better placed to succeed.

The Indian CRO industry is dominated by players focused on offering routine drug development services that are primarily non-differentiated in nature. It is important that Indian CROs position themselves to offer specialized high-value services, address broad therapeutic and product areas and differentiate themselves; to compete successfully in the global marketplace.

Some of the areas and segments that need particular mention are: specialized human trials to evaluate cardiac safety (QTc

studies), radio-labeled mass-balance pharmacokinetic studies, bio-therapeutics drug development and stratified clinical studies based on molecular markers. These areas are gaining prominence, and are important in the drug development context. Inherently, these areas signify new vistas for the CRO industry.

In the Indian market, very few players have the capabilities and infrastructure to conduct such studies. Reliance Clinical Research Services (RCRS), the clinical research arm of Reliance Life Sciences, is one of them.

RCRS has the necessary infrastructure, linkages and competencies to carry out these specialized studies. RCRS hascarried out validation studies in cardiac safety using state-of-the-art systems. It is also in the process of conducting a mass-balance, radio-labeled study. RCRS has conducted several preclinical and clinical studies in bio-therapeutics as also bioassays development, and has demonstrated end-to-end program management capabilities in this segment. In addition, RCRS has completed, and is conducting several clinical research studies for stem-cell therapies, which is another important category in bio-therapeutics. It also has capabilities in carrying out embryo-toxicity based drug screening. RCRS has the ability to leverage the molecular medicine capabilities of Reliance Life Sciences to develop stratified clinical research studies.

An important aspect of developing specialized study capabilities is competency development. The Reliance Institute of Life Sciences, a not-for-profit organization, has been conducting one-year Advanced Diploma Programs to address this need.

As the global pharmaceutical industry consolidates, the opportunity space for specialized CROs would increase significantly. India has been a destination for clinical research, but there are other countries and regions, such as China, East Europe, Latin America and Africa, that can offer competitive options in clinical research. It would, therefore, be imperative for CROs in India to create differentiated plays to sustain and grow. Indian CROs have to seek out, develop capabilities, and conduct specialized studies, to make a mark in the global clinical research league.