BioSpectrum the business of Bio & Health Sciences

It's time to address new challenges

13 September 2011 | News

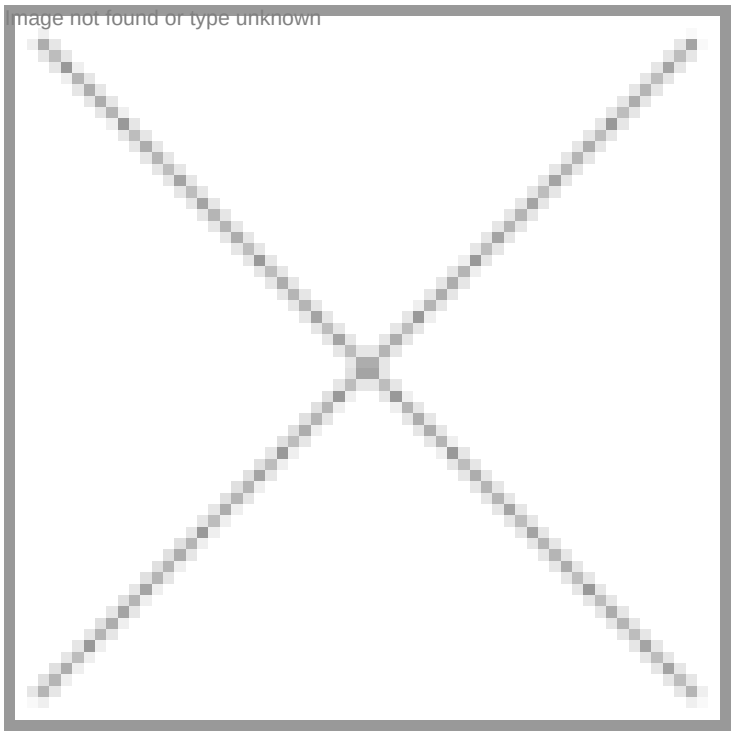

Image not found or type unknown Arun Sundriyal **Mr Arun Sundriyal** Associate director, PPDi	The author is associate director, clinical management, for PPD in India. He holds a master's degree in pharmaceutical biotechnology. He has more than 10 years of experience in clinical research and has worked in vast therapeutic areas such as oncology, neurology, dermatology, respiratory, endocrinology, etc. He can be reached at arun.sundriyal@ppdi.com

The Indian clinical research industry has enjoyed exceptional growth over the past decade because of the country's large population, speed, high quality and cost considerations for conducting clinical research. And while the industry continues to face challenges, the outlook for the future of clinical research is positive and promising.

The contract research industry was virtually non-existent in the country less than 15 years ago, except for a handful of multinational pharmaceutical companies that conducted studies to provide regulatory and medical marketing support to their respective parent companies. Only a few renowned doctors served as investigators for global studies with direct oversight provided by international sponsors.

CROs have entered India in the last 10 years and the industry has expanded rapidly. With competition and escalating costs prevailing in the global market, many companies expanded into emerging markets such as India. Major CROs and biopharma companies began setting up clinical operations in the country targeting the large population.

According to the clinical trial registry website, since its establishment in June 2007 when it was established, more than 1,800 trials have been registered and initiated. Now, most CROs consider a presence in India key to their overall clinical research and development strategy. Key factors continuing to drive growth today are:

- High-quality infrastructure and resources, such as well-educated, English-speaking investigators and clinical research professionals.
- Growing regulatory support from the government and better policies for multinational biopharma, such as 100 percent foreign direct investment (FDI) in the pharmaceutical sector and the exemption of import duties on clinical trials supplies
- Improvements in intellectual property policy.

India offers sophisticated logistics and clinical research infrastructure. There are more than 15,000 hospitals, 900,000 hospital beds and 14,000 diagnostic laboratories across the country. Quality at these locations continues to grow with more than 600 international conference on harmonization/good clinical practice (ICH GCP)-compliant sites now available. In addition, according to the Medical Council of India (MCI) website, more than 335 medical colleges in India are producing 32,000 graduates every year, increasing the availability of qualified talent.

Beyond the nation's medical infrastructure, clinical trials are now supported by full service CROs that are drawing from a growing pool of in-country talent to provide aligned services across areas like data management, medical writing, pharmacovigilance, site management, regulatory consultation and global central laboratories.

While most CROs now offer integrated services in India, others offer clinical monitoring, project management, regulatory, data management and quality assurance services locally, providing services like central labs and IVRS via support teams located elsewhere. The growth of regulatory services in India has also expanded and now includes clinical trial approval for phase I to IV studies, import license, export no objection certificate, marketing authorization, and regulatory consultation among others. Regulatory teams generally consist of regulatory associates, regulatory managers and a regulatory director.

Dossiers are prepared by regulatory associates and reviewed and submitted by regulatory managers and directors. These departments either work under Indian operation or report to global regulatory departments. There are also dedicated regulatory service providers that serve CROs and sponsors.

Issues to be addressed

The Indian clinical research industry still faces some challenges. Sponsors can experience unpredictable delays during regulatory approval and multiple queries after dossier submission, compensation pay out issues, approval and rejection/queries on documents, which required only notification as per current guidelines like approval of Investigator Brochure (IB) and addition of sites.

These issues are a major concern to industry leaders and have been shared with the government. The authorities are taking many steps. For example, a separate chapter of the Drug and Cosmetic Act will be introduced to reduce the risk of liability for sponsors and CROs.

Then, Schedule Y will have the following extensions:

- Schedule Y1- Registration of CROs,
- Schedule Y2- Guidelines for Clinical Trial Inspections and
- Schedule Y3- Guidelines for the EC/IEC.

The Central Drugs Standard Control Organization is also developing a guideline for clinical investigator certification.

Strong outlook

Although there has been tremendous growth in clinical trials over the past decade, the issues above may slow down growth in the short term. The Indian government is taking steps to resolve the above issues. These improvements, along with India's advanced infrastructure and massive patient population, will continue to drive growth in the industry over the short and long term.

With more than 150 CROs in India today, the market for clinical trial outsourcing remains high. The CRO industry is maturing and remains competitive. It will be further aided by openness and regulatory developments as well as by awareness and education provided by CROs and sponsors. This education will help in addressing ethical issues and in developing an overall positive impression about clinical trials. Clinical research is an indispensable part of the drug development process, and India has a large potential to contribute in this process.