BioSpectrum the business of Bio & Health Sciences

Govt steps in to speed growth

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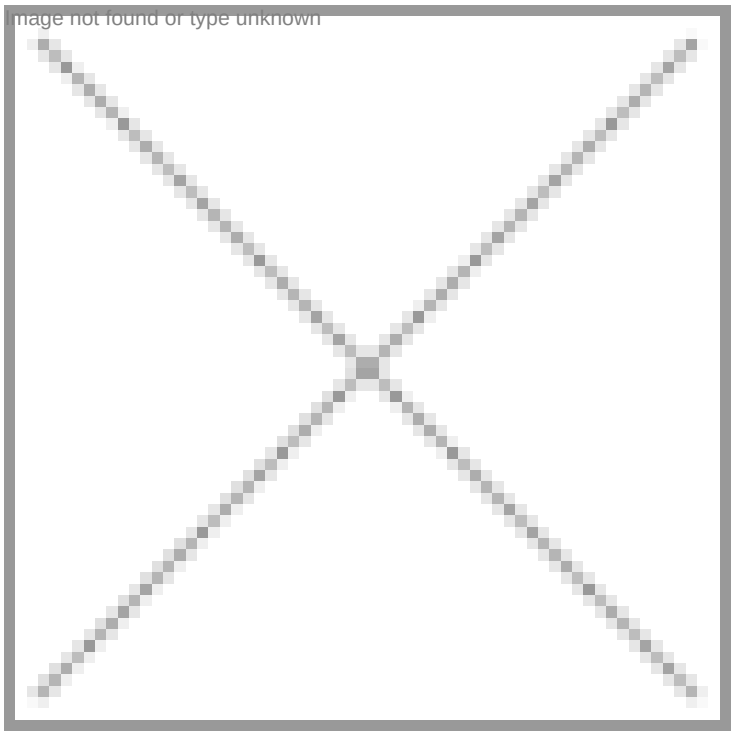
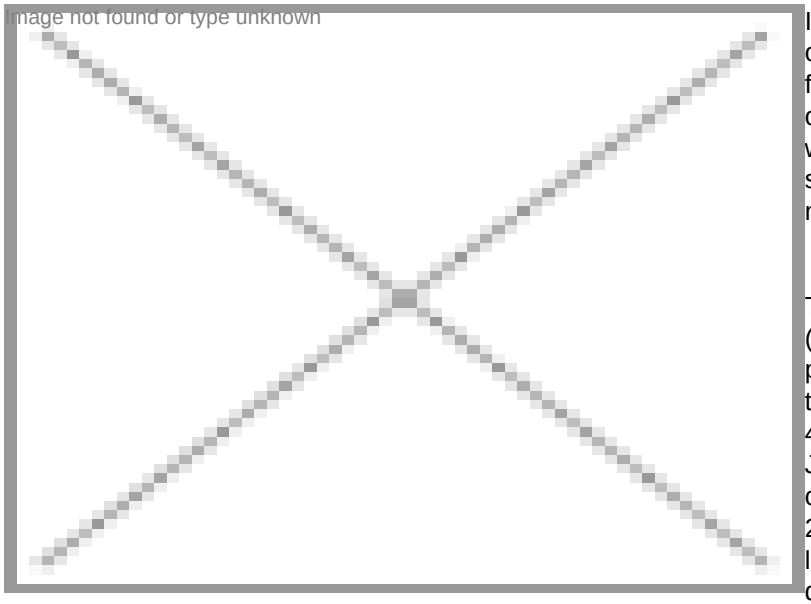




India has become a favored destination for organizations to conduct clinical trials. The key factors for this can be attributed to easy access and availability of a large, diverse and therapy-näive patient population, with a vast gene pool and lower cost of technical services, resulting in lowest per patient trial cost. The number of trials being conducted in India has increased

The Central Drugs Standard Control Organization (CDSCO), India's main regulatory body for pharmaceuticals and medical devices, has permitted the Clinical Research Organizations(CROs) to conduct 401 trials in 2007, 521 in 2008, 453 in 2009; and as on June 2010, 251 trials have been permitted. The number of trials include both the global and local trials The year 2008 witnessed a significant increase in the number of local trials, over the previous year. And this number has dropped slightly in 2009. On the other side, the number of global clinical trials remained more or less at the same level in the last three years.

On August 6, 2010, Union Minister of Health and Family Welfare, Government of India, Ghulam Nabi Azad said in the Lok Sabha that a substantial number of clinical trials were permitted as part of global clinical trials and local clinical trials for

marketing authorization, during last three years in India.

The CDSCO permitted 259, 246, 258 and 117 global trials in 2007, 2008, 2009 and up to June 2010 respectively. The number of local clinical trials permitted for 2007, 2008, 2009 and up to June 2010 were 142, 275, 195 and 134 respectively. These numbers do not include Bio Availability/Bio Equivalence/type trials. More than 100 CROs are working on clinical trials in India.

No company in India can initiate any clinical trial of a new drug without prior approval from CDSCO, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. Clinical trials are permitted in the country as per Rule 122DA, 122DAA, 122DB 122E and Schedule Y of Drugs & Cosmetic Rules.

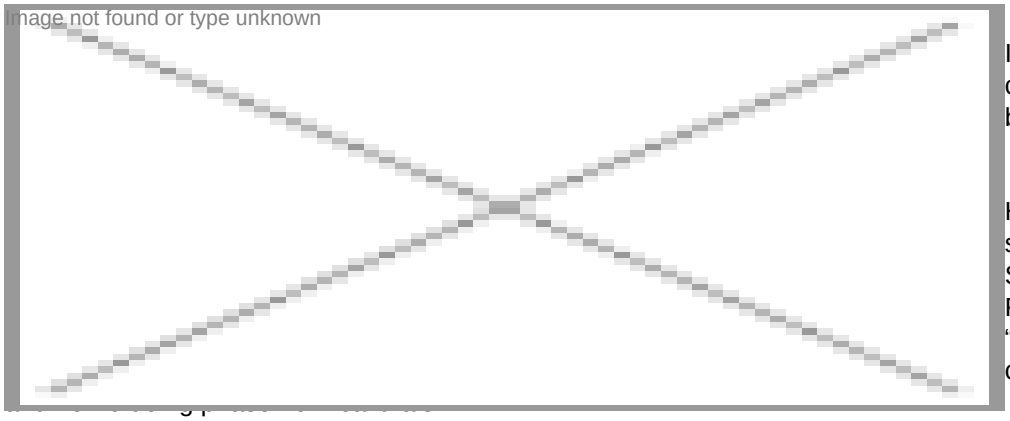
There are a large number of pharmaceutical companies and CROs like GlaxoSmithKline, Johnson & Johnson, Sanofi-Aventis, MSD, Eli Lilly, Novartis, Bristol Myers Sqibb, Bayer Healthcare, Astra Zeneca, Pfizer and clinical research organizations (CROs) like Quintiles, ICON, GVK BIO Siro Clinpharm, Parexel, PRA International PPD, Covance, Omnicare, Kendle are seeking permission from CDSCO to conduct clinical trials in the country.

Today, most of the big pharmaceutical companies are conducting multi-centric trials in India, with some of them operating for more than 15 years. Eli Lilly and Pfizer are one of the earliest big pharmaceutical companies to conduct clinical research in India, and commenced their captive operations in 1995. This was followed by a clutch of other companies in the early to mid 2000, like, Sanofi-Aventis, Bayer, Novartis Astra Zeneca and Johnson & Johnson. The last two to three years have witnessed increased presence of other big pharmaceutical companies, like, Merck, GlaxoSmithKline, Bristol-Myers Squibb, and some of the larger biotechnology companies, like, Amgen, Biogen Idec. These companies are looking to India for almost all therapy areas.

Most of the leading global CROs have set up services in India-Quintiles, PPD, Kendle, Covance, PRA International, Criterium, Chiltren, Omnicare, ICON International, I3 Research, Parexel, iGate Clinical Research, Medpace, Makrocare, Excel Life Sciences, Clinsys Clinical Research, Pharma Net-and are linking India to the global network, strongly.

Some of the leading local CROs in India include ClinInvent, CliniRx, Synchron, Karmic Life Sciences, Accutest, ACT,CliniRx, Max Neeman CRO, Semler research, Vedic Life Sciences, Siro Clinpharm, Lambda Therapeutics, Ecron Acunova, GVK Biosciences, Reliance Life Sciences Clinical Research, Clinace, Lotus Labs, Clinigene International, Vimta Labs Ltd, Synchron Research and Veeda CR.

The CROs such as Raj Biotech, INTOX, Jai Research Foundation, Bioneeds, Vimta Labs, Indian Institute of Toxicology, ClinTech Research India, Sheron Biotech, International Institute of Biotechnology and Toxicology (India), SGS India, Clintox Bioservices, Dabur Research Foundation, Advinus, RCC and Vivo Biotech are specialized in conducting preclinical studies.



In India, most CROs focus on conducting phase III and IV studies, because of the development

However, the CROs are gradually seeing a shift to phase III trials. Dr Sanjeev K Chaudhry, CEO, Super Religare Laboratories Ltd noted, "There are more than 50 CROs conducting phase II-IV clinical trials

Meanwhile, Dr Apurva Shah, group Managing Director, Veeda Clinical Research said that about 2-3 CROs are doing phase I trial, 15-20 CROs are involved in phase II trials, 12-15 CROs are involved in phase III and 20-25 CROs are doing Bio Avaibility/Bio Equivalence (BA/BE) studies.

"Most CROs carry out phase II-IV studies. Very few CROs carry out phase I studies. BA/BE is a different segment. The number of BA/BE CROs could be around 100," observed Dr Arun Bhatt, president, ClinInvent.

Meanwhile Dr Anand Bidarkar, vice president, Business Development, Siro Clinpharm, noted that the Indian CROs are doing 100 phase I studies, 300 phase II studies, 650 phase III studies and 120 of phase IV studies."

In terms of key therapeutic areas, the CROs are focusing on oncology, neurology, respiratory, diabetes, anti-infective, psychiatry, endocrinology, central nervous system, cardiovascular system. Diabetes ranks first as a vast majority of the population are diabetic.

Currently, India has about 1500-2000 clinical investigators. The present growth in investigator sites is around 30-40 percent per year. Dr Arun Bhatt of Clininvent said," If we want to increase the number of sites faster, the industry and government will have to train new sites on a war footing."

Ms Nidhi Saxena, founder and CEO, Karmic Life Sciences, observed that there is a shortage of trained clinical investigators but no specific number can be put. Commenting on the demand side, Dr Anand Bidarkar of Siro Clinpharm said, "We need three times the figure mentioned above."

Sharing similar views, Dr Apurva Shah of Veeda Clinical Research said," The industry is growing at the rate of over 30 percent. The industry has an increasing need for investigators trained in conducting clinical trials. Currently, the clinical trials are restricted to some specific institutions/investigator. We have to build the capacity by bringing awareness in people, media, non-governmental organizations (NGOs), about clinical trials, and train them on their responsibility."

Government initiatives

To support the growing CRO industry in India, the regulatory authority, DCGI, has adopted short-term and mid-term goals. It has started adapting itself to meet the demands of the industry, in terms of quality, transparency and accountability of global trials.

Some of the short-term (2008-10) initiatives adopted by DCGI include:

- robust review process for clinical trial proposals
- mandatory registration of clinical trials in centralized clinical trial registry with effect from June 15, 2009
- training of personnel in clinical trials site inspections
- inspection of clinical trial sites to be an ongoing activity;
- checklist of audits developed the number of inspectors being strengthened
- registration of CROs
- harmonization of regulations on toxicity, definitions of phase 1 consistent with ICH guidelines
- support development of regulations and infrastructure for early stage First-in-Man studies (phase 0 or micro-dosing).

In addition to this, DCGI has mid-term strategy (2011-12) that includes guidelines for registration of ethics committees/IRBs, registration of ethics committee; registration of investigation sites and investigators; GCP training of investigators by an accredited body; penal provisions for violation of clinical trial regulations under consideration; conducting micro-dosing studies (that is, First-in- Man or phase 0). Some of the recent initiatives by DCGI underscore the fact that the regulatory agency is becoming more pro-industry, more vigilant and more efficient, which is the need of the hour.

The growing CRO industry has brought a significant change for the betterment in medical practices, patient access, and patient care. Currently, the clinical research scenario in the country is at an inflection point, and all the stakeholders including regulators, need to reassess their strategy in terms of the latest global developments.

The Indian CROs have to seek out, develop capabilities and conduct specialized studies to make a mark in the global clinical research space. For India to remain a key to the global clinical trials market, pharmaceutical companies, CROs, site management organizations (SMOs), policymakers and academia need to work together, to address many challenges that will bring greater quality and efficiency to conduct global trials in India.