Current Scenario of Clinical Research in India-Need more Education and Training

According to official reports "In 2005 around 100 clinical trials had been approved in the country by the Drug Controller of India (DCI). In 2006, it increased to around 150 and to 240 in 2007.In the current year around 450 have already been approved" Joint Drugs Controller of India, A.B Ramteke said on the sidelines of a conference in Mumbai.

New Delhi, Delhi, IND, 2008-11-25 15:35:34 (IndiaPRwire.com)

India emerged as a global hub for clinical research. According to a report by Mc Kinsey the global Clinical trial outsourcing opportunity in India in the pharmaceutical industry is estimated to be around $2 billion by 2010 and there will be the demand for more than 10,000 investigators trained in Good Clinical Practice (GCP) and 50,000 clinical research professionals.

Analysts project that by 2008 an estimated 30 % of global clinical trials are being undertaken in developing countries. In India alone the clinical trial market of $300 million is expected to grow to nearby $2 billion 2012. In terms of cost efficiency India is better, as the cost of conducting a trial here is lower by 50-60% than in the United States or the European Union. More importantly due to the large naïve patient pool the recruitment rate can be greatly accelerated which in turn leads to shorter study duration. This provides as major advantage in terms of shortening the time to launch a new drug in the market. Based on these advantages, the number of clinical trials in India is expected to grow exponentially over the next five to ten years.

According to official reports 'In 2005 around 100 clinical trials had been approved in the country by the Drug Controller of India (DCI). In 2006, it increased to around 150 and to 240 in 2007.In the current year around 450 have already been approved' Joint Drugs Controller of India, A.B Ramteke said on the sidelines of a conference in Mumbai.

Certain recent changes in regulatory affairs encourage clinical trials in India. In 2005, Schedule Y of the Drugs and Cosmetics Act was amended. Earlier foreign drugs trials could be conducted only at one phase below the highest phase of testing abroad. Now, parallel global clinical trials are possible in India. Permission is granted for concomitant phase 2 and Phase 3 trials. There is a need at the present time for a strong centralized regulatory regime which can give high quality development of ethical capacity, with extra vigilance but with an informed understanding of acceptable risk.

The increase in clinical trials also has challenges like regulatory uncertainties about time to approval of biotech products and for processing import/export licenses, and several other factors are hurdles in planning a clinical trial. Lack of potential investigators with fundamental knowledge of regulatory, ethical, GCP guidelines to conduct clinical trials.

While India is in its own stand in Clinical research most of the medical schools lack a formal course in training for clinical research, so there is a shortage of trained manpower. India has 500 to 1000 investigators in the country as compared to 50,000 in the United States. In a country, which boasts a large medical fraternity, only 400-500 investigators sites have taken part in global GCP trials. The efforts of government and industry to create awareness through GCP workshops and to provide training to the investigators and ethics committees go a long way towards creating a culture of global GCP quality trials.

Despite all these issues most pharmaceutical companies are conducting multicentre studies in India with the establishment of small Clinical research departments in the country. This team coordinates with its global project management or outsourcing partner. The outsourcing decision for these global studies are mostly made in US and Europe; however, as India becomes major hub and contributes further to subject recruitment in clinical studies, Indians will play a much larger role in the outsourcing process. But this calls for the development of its capacities and capabilities in terms of infrastructure, Regulatory structure and formulation of a specialized pool of research investigators. Increasingly, a need is being felt for the development of institutes that may provide training and education in the clinical research segment and meet the growing demands of skilled manpower by the industry.

Until recently there were no structured, formal training courses focusing only on clinical research .The training efforts by the CROs and pharmaceutical companies have shaped the profession. Looking at the prospectives many private training institutes have launched in various classroom based and/or online courses in clinical research management. Institutes like Cliniminds (www.cliniminds.com) are offering a high quality, wide range of clinical research training and education solutions; classroom ,online/distance and E-learning (video conferencing based) viz, Investigators program, Program for CRC/CRAs; Advanced Post Graduate Program in Clinical Research; Post Graduate Program in Pharmacovigilance; Qulaity Assurance; Biostatistics; BA/BE Studies; Regulatory Affairs and several other programs. Cliniminds programs are offered for both clinical research & pharma professionals and for medical /Lifesciences/pharmacy graduates and post graduates who wish to make clinical research their career option and this programs are well integrated with the industry.

- END -

Cliniminds was established in year 2004, by a group of professionals from Clinical Research, Pharmaceutical industry and Healthcare industry with rich and varied experience at top levels. Company was set up with the objective to offer training solutions in the field of clinical research, pharmaceuticals and healthcare.

Cliniminds is an innovative training company providing a wide range of clinical research related training solutions to the students, pharmaceutical companies, CROs and healthcare companies in India and other parts of the world.

Cliniminds - Acadmey for Clinical Research Training & Management, offers wide range of full time, part time, class room, online & distance learning certificate / diploma programs, workshops & seminars. Programs have been designed both for fresh graduates/post graduates and working professionals to equip them to grow professionally in this burgeoning field of clinical research.

For more information, Please contact:

Jitto Thomas
Senior training Coordinator - Cliniminds
+91- 11- 4242 7800 ,+91-9873888671
+91- 11- 4242 7802

You can also visit www.cliniminds.com for more information.