

No clinical trials, no new drugs: Where is this going to lead India?

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In the midst of draconian regulations and uncertainties encircling the Indian clinical trial scene, the Indian Society for Clinical Research (ISCR), a body which primarily represents the interest of all stakeholders in the clinical research, organized a press meet on January 9, 2014, as a kick-starter for its two-day 7th annual conference themed, *'Clinical Research at Crossroads'*, happening from January 10-11, 2014, at The Lalit Ashok, in Bangalore.

Eminent academician and clinical pharmacologist Padmashree Prof Ranjit Roy Chaudhury will be the guest of honor at the two-day conference along with distinguished clinical research professionals who will discuss the recent developments in clinical research across the globe, and create a forum to help clinical research professionals to appreciate what is happening in India and take some of the best practices and implement them in the country.

India has about 16% of the world's population and 20% of the global disease burden. However, only less than 1.5% of global trials take place in the country.

Ms Suneela Thatte, president, ISCR, who was at the press meet said that the media is an important stakeholder in this regard, and that it should send across the right message about clinical trials, which has the ability to bring new medicines to meet unmet medical needs.

She said, "Media brings an important role in bringing about awareness about clinical trials and patient rights, ensuring the

voice of clinical researchers and stakeholders are heard by policy makers."

"In our country, we deal with traditional diseases like malaria and TB, nutritional diseases and the diseases of developed nations like hypertension, cancer and diabetes. We don't have enough vaccines to take care of the population to fight new and emerging diseases," Ms Thatte further added.

Dr Arun Bhatt, president, Clininvent, added, "To develop drugs and medicines, one has to do research and conduct clinical research. It takes more than 10 years to develop new drugs and about 5 years for clinical trials. It doesn't happen over a short period of time. Trials have significantly dropped by 50% compared to what it was."

Dr Suresh Menon, chief scientific officer, Novartis, who was also present at the event opined, "People need to understand why clinical research is being done. The medicines have to be tried out in different phases or steps. Without clinical trials, we will not be able to introduce and make available new medicines for life threatening diseases for patients."

Talking about the significance of clinical trials, "A lot of drugs have been discovered in the last three or four decades to manage diseases effectively. Without clinical trials science cannot really progress. The crux of the real challenge in 2013 was the delay in the approval of research proposals at government level," added Dr Menon.

He believes that 2014 will bring exclusive clarity in norms and the government's support will make it possible for new medicines being made available to patients in India much earlier than how it is today.

Dr Prem Pais, professor of medicine and head division of clinical research and training, St John's Research Institute, touched about the value and role of clinical research in India.

"Clinical research means doing research in which a human being is involved. It is not just about the medicines. Clinical research done on animals in laboratory is not clinical research. All of us want to protect the rights and safety of patients all over the world. India has been doing clinical research in a big way in the last 10 to 12 years. However, countries like US have been doing it since 1950s. The new regulations that have come in is making it difficult for many clinical researchers causing uncertainties," said Dr Pais.

The current clinical trials regulations in India has made many international organizations like National Institute of Health (NIH, USA), Canadian Institute of Health Research (CIHR, Canada), Medical Research Council (MRC, UK) and The Wellcome Trust (UK), withdraw their clinical trials in India and have pulled out of the country owing to the uncertain regulations.

"In the long run, through clinical trials we'll be able to discover what causes diseases and see which treatment works and which doesn't," added Dr Pais.

In conclusion, Dr Suneela added, "Unless trials happen, drugs cannot be marketed in India. Drugs have to be studied in different genetic population. We'll have discoveries going on in the rest of the world, but Indian patients will continue to remain deprived."