

## Confidence building measures must for clinical trials in India: Experts

24 July 2015 | News | By Rahul Koul Koul

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The Indian Society for Clinical Research (ISCR) has stated that in the recent times, several steps have been taken by the Indian regulators to bring clinical research in India back on track. The robust and streamlined guidelines as well as systems are now in place in the country for conducting clinical research.

However, it is being felt that there is also now need to restore confidence among all stakeholders. Given that India has the highest disease burden in the world, it seems only logical that the country should have a clinical research agenda of her own. On the contrary, despite being home to 17 percent of the population of the world and having a fifth of the world's disease burden, the Indian contribution to global drug trials is less than 1.5 percent.

As per the statement of ISCR, there are thousands of patients, desperately waiting for new therapies and drugs to enter the market. In a media roundtable organized at All India Institute of Medical Sciences (AIIMS), the experts deliberated on the latest scenario. They maintained that the clinical research fraternity is not against regulation but there is a need to ensure that there is a strong regulatory framework rooted in the principles of science and research with quality, ethics, patient safety and confidentiality as its guiding principles.

"Clinical research has not got the right perspective in the Indian context which has actually deprived our country from some very imperative and relevant research being ignored," said Samir Sethi, President, Indian Rett Syndrome Foundation and parent of a daughter diagnosed with Rett Syndrome. "While we have the requisite expertise, infrastructure and need in the country, however, certain factors have not permitted clinical research to grow as it should have. We hope that as the regulatory environment improves, a new dimension would unfold between the regulators and the patients, pushing clinical research not only by researchers and scientists in the country, but also as a preferred destination from overseas sponsors. Our children have a right to live with dignity and in an environment where there are investments being made in clinical research that could help them lead a better quality of life. We seek the support of the media in highlighting the cause of rare diseases in India and the challenges of patients living with illnesses for which there is no known cure."

Prof Y K Gupta, Professor and Head, Department of Pharmacology, AIIMS, & Executive Council Member, ISCR said, "Clinical research is essential not only for developing medicines for emerging health concerns (such as XDR TB, antibiotic resistant pathogens, H1N1, Ebola virus, etc.) but also for finding safer and better medicines for entrenched diseases such as HIV, malaria, diabetes, hypertension etc. India, with its large patient population, unmet health needs, and limited resources, needs to make newer and better treatment options available to its population in a quick, economical and dependable manner. For this, India must take a proactive part in clinical research and assume leadership role globally. We must ensure that clinical research in our country is carried out as per global scientific standards, is moored in sound ethical foundations befitting a liberal democracy but is optimally oriented towards addressing national medical and health needs."

"Events of the past have eroded the confidence of various stakeholders in conducting clinical research in India. The science of clinical research will be negatively impacted if we do not stabilize the environment for clinical research in the country soon enough. We have an obligation to ensure that patients have access to the best and most advanced treatment, made possible through clinical research, to alleviate their suffering," said Dr Shamsheer Dwivedee, Head and Director, Department of Neurology, Fortis Memorial Research Institute, Gurgaon.

"For many patients, time is of essence. I have personally experienced challenges in trying to access a clinical trial for my wife which was the only treatment option available for her," said Vivek Tomar, husband of a patient suffering from lung cancer. "For many patients, participation in a clinical trial can make a difference between life and death. Patients cannot wait and it is important for us to remember this. We need an environment that encourages and fosters clinical research so that patients like my wife can benefit."

"There is a need to acknowledge the role of clinical trial patients who are unsung heroes and highlight their experiences and struggles, particularly those suffering from unmet medical needs. We need to build an environment that fosters clinical research, drug discovery and innovation through public education and awareness," said Suneela Thatte, president, ISCR.