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Supreme Court satisfied with new clinical trials approval process

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The supreme court has expressed satisfaction with the process of approvals that were set in place for the trials approved since January 2013 and has asked that all trials approved before December, 2012 to have similar clearances to ensure the safety of patients in a clinical trial and minimize serious adverse events. The court was hearing the PIL filed earlier by NGO on October 21, 2013.

"We appreciate that the Honourable Court considered the 162 cases for which approval has been given by the DCG(I) since the New Drug Advisory Committees were formed in 2011", said the spokesperson of ISCR while reacting to the remarks. "This is an encouraging development and we are glad that the Court and the regulatory bodies are taking measures to ensure the implementation of a robust regulatory framework. As a professional organization representing clinical research professionals across the stakeholder spectrum, ISCR is fully supportive of the need for a more transparent and regulated environment for the conduct of clinical trials in India which ensures the practice of the highest standards of ethics and quality and where patient rights and safety are protected."

Spokesperson also refered to previous ISCR note dated October 4, 2013 where it was mentioned that the value and role of clinical research in ensuring better and more effective treatment for several thousands of patients in India is often overlooked. "It is only through clinical research that we have found and will be able to find newer and better medicines to treat our population and reduce mortality rates for various diseases, including those unique to our part of the world," stated the ISCR's latest note.

The government of India sponsored Working Group on Disease Burden for the 12th Five Year Plan refers to the "triple burden of disease" that developing countries like ours are facing arising from communicable diseases, emerging non-communicable diseases related to lifestyles and emerging infectious diseases. In the larger context of India's unique healthcare requirements and the growing incidence of endemic diseases and emerging lifestyle diseases, we need clinical research to develop new and effective medicines and vaccines to tackle our mammoth disease burden and unmet medical needs. India has 16% of the world's population and 20% of the global disease burden and yet, less than 2% of global trials take place in India. If we have to find better and more cost effective cures for these diseases in a population that is multi-racial and heterogeneous, it is necessary to conduct clinical research in India.

The Indian Society for Clinical Research (ISCR) is an association of clinical research professionals that aims to build awareness of clinical research as a specialty in India and to facilitate its growth in the country while helping to evolve the highest standards of quality and ethics.