

DCGI notification on academic research will boost local research...: ISCR

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The Indian Society for Clinical Research (ISCR), the nodal clinical research professional association in India, has said that the recent March 16th Gazette Notification by the Ministry of Health & Family Welfare¹ regarding exemption given to academic trials approved by the Ethics Committee for a new indication, new route of administration, new dose or new dosage form of approved drug formulations, would give a much needed boost to institutional research being conducted in India.

"Our academic and teaching institutions are engaged in path-breaking research that addresses the unique health challenges of our country," said Dr Shashwati Pramanik, Chair, Regulatory Council, ISCR. "The work they are doing is helping create not just new and better treatment for diseases endemic to our region, but is also making them more affordable and accessible to patients. The recent amendment will significantly reduce start-up timelines due to exemption from DCGI approval while maintaining vigilance through Ethics Committees. Thus, this will give a big fillip to these institutions, encouraging more medical practitioners to get involved in clinical research. A focus on patient safety and Good Clinical Practices must continue to be the guiding principles of such research."

Currently, the research being done in India is insufficient to address the country's growing disease burden.

India has 16 percent of the world's population, 20 percent of the global disease burden and yet less than 1.4% of global research is being done in India.

A greater focus on clinical research is needed in many disease areas where there are unmet medical needs.

Regulatory amendments that encourage research and innovation such as this amendment can pave the way for more breakthrough research.

"If we have to tackle India's unmet medical needs, we need to make clinical research work for our country. Academic and investigator-initiated research is an imperative not merely an option in India. We are pleased that the Government has provided certain exemptions to academic research which will further encourage academic research in our country," said Dr C S Pramesh – Professor and Chief, Thoracic Surgery, Department of Surgical Oncology at Tata Memorial Hospital.

He further added, "Academic research is done to the same stringent local and international guidelines as research done by any sponsor in the country and with equal commitment to patient safety, ethics and quality. We have seen the tremendous benefits that cancer patients at Tata Memorial Hospital have derived from local academic research, both in terms of cost and

efficacy and will continue to invest in bringing better and more cost effective treatments to patients."