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Balanced debate needed on clinical research: ISCR

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While ISCR mentioned that it cannot comment on the specifics of this case without access to all the relevant information, it stressed on the commitment to ensure that clinical research is conducted in India in an environment where quality and ethics and patient safety are not compromised.

As per Ms Suneela Thatte, president, ISCR, "As in every profession and industry, there could be players who operate at both ends of the spectrum. While we do not condone any irregularities, we would also like to acknowledge there are several hundreds of clinical trials taking place in the country in compliance with international and local guidelines. There have been over 40 US FDA clinical trial inspections in India with no critical findings reported. There have also been several European regulatory audits of Indian clinical trial sites, again with no findings indicating impact on patient safety and data integrity."

The clinical research ssupport body has also cited global studies have also shown that there is no difference in the quality of data across regions, including India.

As further iteration of its commitment to the highest standards of quality and ethics, ISCR has developed a 'Code for Conduct of Clinical Research in India'. The 12 point patient-centric code applicable to all ISCR members covers ethical, scientific and regulatory compliance while engaging in any clinical research activities. (Code of Conduct Attached)

The clinical research industry in India has, over the last couple of years, been challenged by a difficult and unpredictable regulatory environment with the number of clinical trials being done in the country slowing down. In the more recent past, there have been various steps put in place by the Ministry of Health and Family Welfare to strengthen the regulatory governance over clinical research in India. ISCR is fully supportive of these initiatives to create a more robust and regulated environment which ensures the practice of the highest standards of ethics and quality and where patient rights and safety are protected.

Given India's increasing burden of disease, there is an urgent need to restore confidence and trust amongst global stakeholders in doing clinical research in India and foster an environment and ecosystem that encourages clinical research. India has 16 percent of the world's population, 20 percent of the global disease burden and yet less than 1.5 percent of global research is done in India. We seek the media's support in bringing a more balanced debate to the discussion on clinical research in India. Even as there may be violations and deviations which are far and few between, there are robust guidelines in place for the conduct of clinical research in India. It is only through clinical research that newer and better treatment options can be made available to Indian patients, critical particularly for illnesses where there is an unmet medical need.