Press Release
For Immediate Publication

ISCR Voices Optimism for Clinical Research in India Amidst Evolving Regulatory Landscape

- **Patient Centricity and Research for India to be key focus of 9th Annual Conference**
- **Clinical Research Stakeholders Share Outlook for 2016**

Mumbai, January 6, 2016: Underscoring the role and relevance of clinical research in meeting the needs of patients in India and the value that clinical research can derive for all stakeholders, the Indian Society for Clinical Research today announced that the theme of its 9th Annual Conference is **Clinical Research in India: Patients First and Research for India.** The Conference is being held in Mumbai on January 8th & 9th and is expected to be attended by around 400 clinical research professionals from India and overseas.

Over the last few years, clinical research in India went through a very turbulent period. Hard-hitting revisions in compensation guidelines in January, 2013 negatively impacted the growth of clinical research in India before more rational guidelines in 2015 restored some balance in the regulatory environment. The strengthening of the regulatory-ethical-operational framework for conducting clinical research in India has led to an ongoing process of streamlining and stability. It is against this background that the theme of the ISCR Conference assumes significance.

Although home to a sixth of the world's population, less than 1.4% of global clinical trials is done in India, a country which also has a fifth of the global disease burden. More needs to be done. Clinical research is essential not just for developing medicines for emerging health concerns such as antibiotic resistant pathogens, H1N1 and dengue but also for finding safer and better medicines for endemic diseases such as malaria and tuberculosis, as well as for lifestyle diseases now becoming more entrenched in the country such as diabetes, hypertension and cancer. A patient-centric approach guided by doing research in therapeutic areas most needed for our patients and in a manner that is best suited to our patients, with a focus on safety, ethics and quality is the underlying message expressed in the theme **Patients First**. For this to happen however, India needs to take a more proactive role in conducting clinical **Research for India**. A more conducive regulatory framework for the conduct of clinical research in the country will enable this and encourage local innovation, ensuring that **Make in India** is a reality for the drug development and clinical research sector in India. There is no greater evidence of India's research strength than in the most recent development of the rotavirus vaccine which was a major research breakthrough given that India loses close to 2 lakh children to diarrhoea every year, of which 1 lakh deaths are caused by the rotavirus[1]. Across the country, large medical institutions are also investing in research to meet the

specific needs of our population and these efforts need to be encouraged. **Patients First and Research in India** will result in better, faster and more affordable and accessible treatment for patients in the country.

The forthcoming 9th Annual Conference will cover a vast range of topics of relevance and contemporariness from the perspective of clinical operations, investigator initiated research, accreditation, ethics, training, regulation, pharmacovigilance, medical writing, data management, statistics and career development in clinical research. It will be preceded by a series of pre-conference workshops for clinical researchers and students on accreditation, medical writing, risk-based monitoring and causality assessment.

Given the challenges of the new regulatory environment and the need for all stakeholders to work more collaboratively in shaping clinical research in India, ISCR earlier in 2015 revised it mission statement to stress on the importance of working together with diverse stakeholders to shape and foster an environment facilitating ethical and responsible clinical research for better patient outcomes. Core to this is the need to create greater education and awareness of clinical research and its relevance to India, as also on the rights and responsibilities of patients participating in clinical research. Through NavChetana, an advocacy initiative launched in early 2015, ISCR has been holding awareness sessions on clinical research at various medical and public fora and this will continue in 2016.

ISCR acknowledges the positive changes in the regulatory environment in 2015 and is optimistic and hopeful that with a multistakeholder collaborative effort and ongoing dialogue with the regulators, there will be more clinical research done in India so that patients not just in India, but across the world, will benefit.

Quotes

Ms. Suneela Thatte, President, ISCR says, "*We have come a long way forward since early 2013. India must now take a more proactive part in conducting clinical research to make newer, safer medication more accessible. We hope the regulators will also invest in capacity building and better infrastructure to ensure better governance. The 9th Annual Conference presents a wonderful opportunity for all stakeholders involved in the conduct of clinical research in India to discuss and deliberate on how we move forward in a new regulatory environment and what more needs to be done to facilitate ethical and responsible clinical research in the country.*"

Dr. Suresh Menon, Member, Executive Committee and Regulatory Council, ISCR says, *"Clinical research should not be looked at in isolation of the larger healthcare needs and priorities of our country. We have a great task ahead of us in working together to strengthen clinical research sites, investigators and ethics committees and of course, empowering the patient who is at the centre of clinical research. At the same time, we have a responsibility in working with each other to help restore trust and confidence of global stakeholders in doing clinical research in India. This is an important and immediate requirement."*

Dr. Girish Chinnaswamy, Associate Professor, Dept. of Paediatric Oncology, Tata Memorial Hospital opines, *"When debating about clinical research, we must remember that at the centre of any research we do is a patient. As medical practitioners and investigators, we have an important responsibility to ensure*

that patients have access to the latest and best treatment options. Vulnerable populations, whether children or mentally ill, have equal rights to participate in and benefit from clinical trials. There are stringent safeguards in place to protect such groups and we cannot deny them the opportunity to participate in a trial. In the long run, we need to empower patients so they have more control in decisions governing their health even if it means their participation in a clinical trial."

Dr. C. S. Pramesh, Professor and Chief, Thoracic Surgery, Dept. of Surgical Oncology, Tata Memorial Hospital says, *"As a country, we have a moral obligation to participate in clinical research and a responsibility to our patients. Institutions such as ours have made a lot of investments in clinical research to address the unique needs of our patient population. We need a regulatory environment that will encourage and support the kind of research we do. In the last year, we have seen steps taken by the regulators to address many of the contentious guidelines and hope that the process of reform will continue in 2016 so that ultimately patients will benefit."*

About ISCR

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. To that extent, we are fully supportive of the initiatives undertaken by regulatory authorities to create a more robust and regulated environment in India for the conduct of clinical research and will continue to work very closely with different stakeholders in the development of regulations that will safeguard and protect patients in a clinical trial. For more information, visit www.iscr.org

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References:

1) The Lancet -2013