Press Release
For Immediate Publication

ISCR Conference ends with Renewed Commitment to Patients and Clinical Research for India

- *Positive developments in the regulatory environment welcomed by stakeholders*
- *Notification on Investigator initiated research welcomed as an encouraging sign*

Mumbai, January 11, 2016: The 9th Annual Conference of the Indian Society for Clinical Research (ISCR) concluded on Saturday, January 9th, 2016 with a strong iteration on the importance of clinical research in India to provide better, safer and more accessible treatment for patients. There was also unanimous agreement that the changing regulations in 2015 had provided a fresh impetus to doing clinical research in India even while delegates welcomed the more recent draft amendment to the Drugs and Cosmetic Rules 1945 to encourage academic research.

The second day of the conference focused on topics such as site quality, clinical operations quality, ensuring quality in ethics committee, investigator initiated research, collaborative research and understanding the various career opportunities in clinical research for students and young professionals. Speakers emphasized the need for young talent that is passionate and willing to bring about a change in the clinical research industry. Sessions also focused on opportunities in medical writing, regulatory strategy and operations, marketing, sales, pharmacovigilance/safety and product management.

Ms. Suneela Thatte, President, ISCR said, "*Over the last two days we have deliberated at length on the requirements that will make clinical research go back to its former growth track in India. And I am very pleased with the results of our discussion. ISCR has functioned as both a catalyst and an enabler for the clinical research industry in India. We are fully conscious of the role this industry plays in meeting the unmet medical needs of Indian patients in several disease areas. Our resolve now is to continue with even greater commitment and rigor in this direction. As a society that stands for* ***Patients First and Research for India,*** *we need to ensure that while research on new therapy takes place, it does not happen at the cost of human rights, patient safety and research ethics*."

The highlight of the second day was understanding the purpose of investigator initiated research in navigating the new environment for doing research in India. This session had representation from the heads of industry and academic institutions/hospitals in the country to discuss the changes in regulations and conducting research in times of uncertainty, the challenges faced by various stakeholders in carrying out multinational collaborative research and the value of repurposing drugs for current health needs.

Dr. C. S. Pramesh Professor and Chief, Thoracic Surgery, Department of Surgical Oncology at Tata Memorial Hospital cited examples of investigator-initiated research in India that led to significant outcomes for patients in India while addressing the specific and real needs – accessibility and affordability - of cancer treatment in India. *"If we have to tackle India's unmet cancer burden, we need to make clinical research work for our country. Investigator-initiated-research is an imperative not merely an option in India,"* he said while highlighting the need for increased emphasis on and support for investigator-initiated research. At the same time he spoke of the challenges faced by institutions in carrying out such research which were largely around research methods and funding and suggested the following solutions:

- Improved scientific infrastructure and capacity
- Training at undergraduate level – catch 'em young!
- Systematic research training
- Protected time for research
- Expand clinical trials
- Encourage collaborative research

Dr. Pramesh added, "*We have underestimated and undervalued the impact of investigator initiated research in India and are nowhere close in recognizing its worth. We have had regulatory challenges in the past which have been addressed. I am happy to share that we have a recent Gazette Notification dated 6th January, 2016 which introduces draft amendments in the Drugs & Cosmetics Rules, 1945 that will definitely go a long way in encouraging investigator-initiated research. This is a welcome move."*

In an earlier panel on why site quality is everyone's responsibility, panelists stressed on the importance for investigators in a trial to maintain a balance between being a researcher and a treating physician. They also highlighted that robust regulations, well-functioning Ethics Committees, trained investigators, committed site staff and well informed subjects are all equally important in improving site quality.

The final day concluded with the release of the findings of a research study done at the venue which saw more than a 75% participant response. The findings (which will be released to the media shortly) provided important and interesting insights on perceptions about the current external environment in India and what participants needed to be done to help rebuild a more enabling environment for clinical research in India. Close to 60% of the participants also renewed their pledge to commit to a more ethical clinical research environment in India in a booth that was sponsored by Sanofi India.

The President of ISCR announced that the next ISCR Conference, the 10th, will be held in Mumbai in January, 2017.

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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