



Press Release
For Immediate Publication

Industry & Academic Experts Call for Greater Stakeholder Collaboration in an Evolving Regulatory Environment

- *9th Annual Conference of Indian Society for Clinical Research Inaugurated*
- *Patients First and Research in India focus of the two day deliberations*

Mumbai, January 08, 2016: Hope and optimism for a better future for clinical research in India and patient access to better and more effective medicines was the overwhelming sentiment expressed as the 9th Annual Conference of the Indian Society for Clinical Research (ISCR) that was underway in Mumbai today. Over 400 clinical research professionals from across the stakeholder spectrum were drawn together to discuss and deliberate on the theme '**Clinical Research in India: Patients First and Research for India**' and what more needs to be done to create a more enabling environment for the conduct of clinical research in the country.

Ms. Suneela Thatte, President, ISCR in her welcome address said, *"We have a great responsibility on our shoulders given where clinical research stands today. The last three years were a difficult time for clinical research in India. We at ISCR have worked relentlessly to turn the situation around in favour of clinical research and the positive outcomes are in front of us today. We have seen a series of developments and order relating to clinical research in the country, which has to a great extent helped bring balance in the regulatory environment. The compensation guidelines are more balanced and rational; we are beginning to see more predictable approval timelines with the expansion of the Subject Expert Committees; and the expected roll-out of the accreditation process is projected to have a significant impact on the quality of research. What has been extremely encouraging is the inclusive approach adopted by the regulators whereby stakeholder feedback has been actively sought and acted upon in many cases. We now have a regulatory system that is balanced, aligned with global trends and innovation and addresses our uniqueness as a country and society. This is a significant development, something that we at ISCR hope to build upon in 2016. It now extremely important not to lose sight of quality and compliance as the clinical research industry enters into the growth phase."*

A message was, read on behalf of **Dr. K. L. Sharma, Joint Secretary, Ministry of Health and Family Welfare** who could not join the conference. The message was, *“The Government of India understands the importance of clinical research in India and the industry concerns have been addressed substantially...In areas where we need improvement, the Government is willing to engage with industry stakeholders and academic/research institutions to work out solutions. We are committed to leverage the resources in the public and private sector to ensure cutting edge research in drug related areas.”*

The Conference began on a reflective note with a citation in memory of the late Prof. Ranjit Roy Chaudhury whose visionary leadership and commitment to the progress of clinical research in India led the fraternity through its most challenging times and provided new hope of a regulatory environment built on scientific and rational principles. The citation was delivered by **Prof. Y K Gupta, Professor and Head, Department of Pharmacology, AIIMS, & Executive Committee Member, ISCR**, who hailed the role of ISCR in taking on the responsibility of fulfilling Prof. Roy Chaudhury’s unfinished mission of developing a patient-centric clinical research environment by bringing together various stakeholders on a collective platform. *“Evidence-based medicine has made the single biggest contribution to the practice of medicine in the last fifty years and this has only been possible because of well conducted trials,”* said **Prof. Anil K D’Cruz, Professor & Chief, Department of Head & Neck Surgery, Tata Memorial Hospital**, while delivering an address on Clinical Research to Improve Patient Care – Trials, Tribulations and Success. He drew from several clinical trial case studies to demonstrate the value of clinical research to patients and also highlighted how hospitals that invest in clinical trials provide better hospital care. He also stressed on the need for more investigator initiated research to be encouraged for diseases and illnesses that impact Indian populations to ensure better outcomes.

The conference sessions touched upon topics such as clinical research operations, investigator initiated research, accreditation and understanding the functioning of US FDA advisory committee meetings as also on how technology is redefining the conduct of clinical trials and the use of electronics for the recording and management of health data.

The highlight of the first day was an Industry-Academia Leader’s Conclave, which had representation from the heads of industry and academic institutions/hospitals in the country discuss the impact of the last few years on clinical research in India and what needs to be done to bring clinical research in India back on track to meet the increasing burden of disease in the country. Said **Dr. Rajendra Badwe, Director, Tata Memorial Hospital**, *“We need to ensure a permissive regulatory environment that is patient-centric. Improving patient outcomes is our first and foremost objective and we all collectively work towards ensuring that patients have access to latest therapeutic options for their unmet medical needs. In India, the perception that patients are being used as guinea pigs needs to change.”*

“Our patients cannot be disadvantaged and need to get drugs at the earliest. In addition, we need a scientific temperament to be built in our country and an environment and enabling policy that will foster research,” said **Mr. K G Ananthkrishnan, Managing Director, MSD India**. Agreeing on the need to highlight the contribution of science to society, **Mr. Sharad Tyagi, Managing Director, Boehringer Ingelheim**, said that some fundamental issues like science and its perceived exploitation still need to be addressed and perceptions about science need to change in our country.

“The challenges of the last few years have provided the industry an opportunity to change and innovate in a new regulatory environment. It also brought all stakeholders together on a common platform for the first time which augured well for the industry,” said **Naz Haji, Senior Vice President & CRO Head, Quintiles Research India**. Panellists agreed that building trust and confidence in global stakeholders was an important requirement in bringing trials back to India while also highlighting that investigator and patient testimonials about the benefits of clinical research was also important in creating widespread awareness about the contribution of clinical research to better healthcare and patient outcomes. Industry stakeholders needed to take a more proactive role in building a more favourable environment for the conduct of clinical research in India, which will enable and encourage local innovation and result in better and faster as well as more affordable and accessible treatment for patients in the country.

“The fact that there are so many of you at this year’s Conference is reflective of the optimism and hope the year holds for all of us. While much has been done and more still needs to be done on the regulatory front, it is important that all of us here work collectively to restore confidence and trust amongst global and local stakeholders in doing clinical research in India,” concluded Suneela Thatte. *“We reiterate our commitment to continue our engagement with all of you and work towards creation of a clinical research ecosystem that balances the interests of all stakeholders – particularly the patients. I do hope that our deliberations over the next two days stand a testimony to this intent as we continue our quest for better healthcare for all through innovation and instill confidence in a clinical research process that stands not only for quality and innovation, but also safety and ethics,”* she added.

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

For further information, please contact:

At ISCR:

Melissa Arulappan

media@iscr.org

+91 9845022389

Sunandita Roy

+91-7738142011

Sunandita.Roy@edelman.com