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# Clinical research stakeholders welcome positive steps, hope for better regulations

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Besides welcoming various positive developments, the optimism for a better future for clinical research in India and patient access to more effective medicines was the overwhelming sentiment expressed at the 9th Annual Conference of the Indian Society for Clinical Research (ISCR) held recently at Mumbai.

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 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; the expected roll-out of the accreditation process is projected to have a significant impact on the quality of research. 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 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 or 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," he said.

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 or hospitals in the country discuss the impact of the last few years on clinical research in India and what needs to be done in the next few bring clinical research in India back on track to meet the increasing burden of disease in the country.

According to 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," mentioned Mr K G Ananthakrishnan, MD, MSD India.

Agreeing on the need to highlight the contribution of science to society, Mr Sharad Tyagi, MD, 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," opined Mr Naz Haji, senior vice president and 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 highlight of the second day was to understand 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 or 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.

The final day concluded with the release of the findings of a research study done at the venue which saw more than a 75 percent 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 percent 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 which will be the 10th edition will be held in Mumbai in January, 2017.