The Capital, 1802, 18th Floor, Plot No. C- 70,
'G' Block, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
Tel: 022- 6570 6167 / 6693 2028
Email: info@iscr.org, Website: www.iscr.org

Press Release
For Immediate Release

Advancements in Digital Technology Critical to Advancements in Clinical Trials Say Panelists on Concluding Day of ISCR 14th Annual Conference

India, 22 March 2021: Focusing on the rapid advancements made in digital technology and the accelerated advances in digital health during the pandemic in particular, speakers and panelists across all tracks at the virtual 14th Annual ISCR Conference endorsed the growing relevance and importance of tech-enabled clinical trials in 2021 and beyond. "The overarching themes that were highlighted during the two day event were regulatory flexibility, adoption of digital technology and high degree of stakeholder collaboration during the pandemic all of which points the way forward for our Conference theme **Clinical Research – Transforming Lives: 2021 and Beyond**. Patient-centricity and a focus on safe, ethical and quality clinical research will continue to guide the clinical research community," said Dr Chirag Trivedi, President, ISCR.

"As we think about regulatory strategies and clinical research approaches that make drug development affordable, digital health technologies have the potential to offer the solutions needed to transform clinical trials," said **Dr. Kiran Mazumdar Shaw, Executive Chairperson, Biocon Ltd,** while delivering the keynote address on the second day. "We need to apply and leverage digital health, algorithms, data science and health information to drug development and enable bringing drugs to market faster. This will also result in much more innovation and investments in R&D and clinical trials will explode. With the rise of computing power and the US FDA's stand on digital tools, we are looking at a paradigm shift in clinical research that is focused more on digitization. India must take advantage of the opportunities digital health offers. Let us resolve to shape and build a clinical research world that is predictive, precise and results in better patient outcomes," she added.

The second day's proceedings witnessed power-packed sessions around academic clinical research & pharmacovigilance, effective clinical data management, biostatistics, and statistical programming, and medical writing. Summarizing her views on the year 2020 for clinical trials during a panel discussion on *'Clinical Research – Transforming lives: 2021 and Beyond*,' **Dr. Rubina Bose, Deputy Drugs Controller, CDSCO, said**, "Regulators were at the forefront right from the onset of the pandemic. By taking a Patient First approach, we enabled bringing imported COVID-19 kits for early detection into India at the initial stages. Collaboration across different institutions and government ministries played a crucial role in tackling the pandemic effectively. As everything moved to digital, it allowed us to reduce the timelines for approvals, which was vital for furthering research and trials in the country.

As we move into 2021, we need to continue to ensure resource maximization, transformative use of digital platforms and build capabilities."

While speaking on expectations from stakeholders, she added, "Clear understanding of the regulatory pathway is exceedingly crucial. As data credibility is of utmost importance, researchers must collect, understand, and always validate their data. We are working collaboratively with different scientific and academic institutions and have we have built an ecosystem which must be continued even after the pandemic ends."

The conference also shed light on how various stakeholders were able to incorporate advances in technology to streamline and expedite processes during the pandemic. Commenting on the *National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic*, **Dr. Roli Mathur, Head Bioethics Unit ICMR, WHO Collaborating Centre for Strengthening Ethics in Biomedical Health NCDIR, Bangalore,** said, "The principles of ethics and scope of the guidelines were not only limited to the biomedical realm but were also from a socio-behavioural perspective. The National Guidelines stressed the need for expedited, unscheduled, and virtual meetings as per the requirements. Since digital technology was being enabled, communication on privacy and protection of the data was also a key component."

Across the pharmacovigilance, biostatistics, medical writing and clinical data management sessions, panelists spoke of the digital-enabled regulatory flexibility during the pandemic which had helped bring drugs faster to market and stressed that this needed to continue.

Earlier in day, the National Awards for Excellence in Academic Clinical Research were give to Dr Kavita Singh, Research Scientist, Public Health Foundation of India and Dr Tuhina Banerjee, Prof, Institute of Medical Sciences, Banaras Hindu University under the early career research category, and Dr Bhavuk Garg, Additional Prof, All India Institute of Medical Sciences and Dr Prashant Kumar, Faculty Scientist, Institute of Bioinformatics under the mid-career research category.

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, ISCR is 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
+91 9845022389
media@iscr.org

At Ruder Finn India:
Ishan Sahini
+91 9818602075
sahnii@ruderfinnasia.com

Tanya Sahay
+91 80881 32071
sahayt@ruderfinnasia.com