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Indian Society for Clinical Research focuses on new regulations

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ISCR spells out short term and long term goals

Beyond New Regulations - Increasing Participation and Enhancing Patient Safetywas the theme of the 13th Annual Conference of the Indian Society for Clinical Research (ISCR) held in Mumbai on the 24th and 25th of January, 2020.

The two day event, preceded by six pre-conference workshops, saw around 1000 clinical research professionals from across India and other countries come together to discuss the evolution of clinical research ecosystem in India post the New Drugs and Clinical Trials Rules, 2019, introduced in March last year, and deliberate on what more needs to be done to move India's clinical research agenda forward

"The decade beginning 2010 was a defining one for clinical research in India," said Dr. Chirag Trivedi, President, ISCR. "It was a period that saw the industry go through several peaks and troughs but one that ended on an optimistic note with the introduction of the New Drugs and Clinical Trial Rules, 2019. The new rules brought greater clarity and speed in the regulatory approval process for clinical trials, while ensuring that patient safety was not compromised. We hope that more clinical trials will now be conducted in India to find newer treatment options for the unmet medical needs of our Indian patients." India has the world's second highest population and the highest disease burden and yet, less than 1.2% of global clinical trials are conducted in India (source: www.clinicaltrials.gov).

"Ethical Clinical Research is finally looking up of late with the regulations and guidelines in place. Investigators and sponsors have tightened their shoe laces and India is set to take on the world in this space with the patient at the centre. This conference with the theme *Beyond New Regulations- Increasing Participation and Enhancing Patient Safety*is but a mirror to the real world situation and will be covering all the aspects of clinical research from all stakeholders perspectives," said Dr. Urmila Thatte, Professor and Head at the Department of Clinical Pharmacology, Seth G S Medical College, KEM Hospital, Mumbai.

The 2020 conference of ISCR focused on various clinical trial reforms towards building a strong research enterprise of the future, while also covering discussions on emerging clinical research opportunities in India. Over the two days, attendees had

a choice of attending four parallel tracks focused on Clinical Operations, Clinical Data Management, Biostatistics and Medical Writing.

From deliberations on private-public participation in clinical research to academia-industry collaborative partnerships, to risk-based monitoring and artificial intelligence and machine learning, the Conference covered a wide gamut of topics at the frontier of discussions around clinical research. Stakeholders across the clinical research spectrum, including industry, investigators and ethics committees, discussed how India can build a robust ecosystem that will protect the rights, safety and well-being of participating patients, while enhancing the conduct of quality and ethical clinical trials in the country.

“India must proactively participate in conducting clinical research and assume a leadership role globally so that we can offer newer treatment options for our patients in India and across the world,” added Dr Trivedi. “Towards achieving this and furthering ISCR’s vision, ISCR has identified the following goals:

Short term goals (1-2 yrs)

- Continue confidence building measures and advocacy efforts for all stakeholders
- Increase patient awareness about clinical research
- Work with government, policy makers, regulators, physician and industry associations to further the cause of clinical research in India
- Increase outreach to various stakeholders
- Publish white papers/publications
- Continue clinical research awareness/training programs

Mid-term goals (3-5 yrs)

- Expand from clinical trials to clinical research
- Increase working with academic institutes
- Increase capacity building across stakeholders for e.g., doctors, para-medical staff, hospitals, ethics committees, industry, etc.
- Indian physicians/scientists to be a part of global committees

Long term goals (>5 yrs)

- Increase digital adoption for the clinical research fraternity as well as by patients participating in clinical trials
- Help India lead in global drug development

To achieve these goals, ISCR believes it is imperative that all concerned stakeholders viz., the industry, government, policy makers, regulators, hospitals, doctors, ethics committees, etc. work together to develop the clinical research ecosystem and facilitate drug development in India. The Government can play an important role in facilitating this through formulating and revising policies that will facilitate the conduct of ethical and good quality clinical trials in India, creating a collaborative platform for all stakeholders, building a conducive ecosystem and the infrastructure, undertaking initiatives to support large scale capacity building and supporting innovation in the country for drug development.

“It is an exciting time to be in clinical research in India,” concluded Dr Trivedi, “and we look forward to this decade with hope and optimism and a better future for our patients.”.