

## 11th Annual ISCR Conference: Collaborative Clinical Research for Better Patient Outcomes

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**Collaborative Clinical Research for Better Patient Outcomes** is the theme of the 11<sup>th</sup> Annual Conference of the Indian Society for Clinical Research (ISCR) being held in Bangalore on the 19<sup>th</sup> and 20<sup>th</sup> of January, 2018. The two-day event, preceded by pre-conference workshops, will see over 800 clinical research professionals from across India and other countries deliberate on the collaborative role of clinical research stakeholders in a strengthened and improved clinical research regulatory environment.

“The challenges of the last few years set back the progress of clinical research in India which has impacted patients the most as it has delayed their access to newer and more advanced treatment,” said **Dr. Chirag Trivedi, President, ISCR**. “With more balanced and rational regulations in place, it is important for all stakeholders of clinical research to now discuss and evolve strategies to grow the clinical research environment in the country, while ensuring patient safety as well as high quality clinical research for better patient outcomes.” With the second highest population in the world and a large disease burden (at 20%), less than 1.4% of global clinical research happens in India. “We need to make newer and better treatment options available locally and to patients globally. For this, India must proactively participate in conducting clinical research (“Research in and for India”) and assume a leadership role globally so that we can offer newer treatment options for our patients in India and across the world (“Made for the World”),” added Dr. Trivedi.

“The 11<sup>th</sup> Annual Conference is being held at a very critical time for the Indian clinical research industry,” said **Dr. Ramesh Jagannathan, Chair, Organising Committee, 11<sup>th</sup> ISCR Conference**. “We have a significant task ahead of us in terms of not just strengthening the overall infrastructure for and governance of clinical research in the country, but also in empowering

patients who are at the core of any clinical research activity. **Patients First** is an important ethos of ISCR and our 11th Annual Conference is also a renewal of our pledge to quality, patient safety and data integrity.” Preceding the Conference are two days of workshops on various aspects of clinical research including evidence based medicine, pharmacovigilance, risk-based monitoring, clinical pharmacology and careers in clinical research.

The 2017 [“India: Health of the Nation's States — The India State-Level Disease Burden Initiative”](#) report states that the contribution of most major non-communicable disease categories to the total disease burden has increased in all Indian states since 1990. These include cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, musculoskeletal disorders, cancers, and chronic kidney disease. Diarrhoeal diseases, lower respiratory infections, iron-deficiency anaemia, neonatal disorders, and tuberculosis continue to be major public health problems in many poorer states of North India. “Clinical research is essential not only for developing medicines for emerging health concerns (such as antibiotic resistant pathogens, H1N1, Ebola virus, etc.) but also for entrenched, tropical diseases (such as diseases such as malaria, leishmaniasis, etc.) and lifestyle diseases such as diabetes and hypertension. Given our large unmet health needs and limited resources, we need to make newer and better treatment options available to our population in a quick, economical and dependable manner,” said **Dr. Denis Xavier, Chair Scientific Committee, 11th National Conference and Vice Dean, St John’s Medical College**.

With the overarching theme of *“Collaborative Clinical Research for better Patient Outcomes”*, the topics for the Conference have been deliberately chosen to be of relevance to sponsor, academia and investigator-initiated research and cover various aspects of clinical research conduct involving multiple stakeholders. Given India’s potential to emerge as a big player in data-driven clinical research services, two Conference tracks have been planned focusing on Clinical Operations as well as Clinical Data Management/ Biostatistics/ Medical Writing.

“The great advances in medicine that have occurred over the last 60 years have largely been the result of clinical research,” said **Dr. Prem Pais, Former Dean, St John’s Medical College and an Investigator** in several studies. “Clinical research has not only identified new and effective treatments but has also identified harmful treatments that has saved many lives. As an example, 60 years ago 30 per cent of people who suffered a heart attack died in the first month. Today about 8 per cent do.” Dr. Pais spoke of the need to create more awareness about clinical research so that patients are aware of their rights and the value that clinical trials can offer.

Dr. Trivedi said that it was imperative that the new and improved regulatory environment in India was communicated to the world at large so that more clinical research is conducted in India. A conducive clinical research ecosystem will encourage more research and development and will give an impetus to the Government of India’s ‘Make in India’ initiative. “As compared to 2016, close to a two and a half to three-fold increase has been observed in the number of global clinical trials approved by the DCGI in 2017 which indicates that the recent regulatory changes have had a positive impact but we still need to do more,” he said. He spoke of two major challenges that need to be addressed – the proposed mandatory accreditation of Ethics Committees which if implemented from January 2018 could cause huge operational challenges since majority of the Ethics Committees have not yet applied for accreditation and the need to continue advocacy efforts to create more awareness amongst various important stakeholders about the good that clinical research has done for our Indian patients in fighting their unmet medical needs. “We are as committed to the DCGI’s commitment to making safe, efficacious, affordable and quality medicinal products for our people,” concluded Dr. Trivedi.