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“India should have a vibrant clinical research community who can advise drug developers”

16 June 2021 | Interviews

The Indian Society for Clinical Research (ISCR), an association of clinical research professionals, has announced the appointment of Dr Sanish Davis as its President for the term 2021-23

Dr Davis holds a degree in Clinical Pharmacology and has 15 years of experience in the clinical research industry. Currently serving as the R&D Director, Global Commercial Operations (GCO)-India at Johnson & Johnson, he has taken over from Dr Chirag Trivedi who was the President of ISCR for two terms from 2017-2021. BioSpectrum reaches out to Dr Sanish Davis, President, Indian Society for Clinical Research (ISCR), Mumbai to talk about the growth and challenges in store for the clinical research sector in the post-covid world.

Edited excerpts;

What new initiatives have been taken to protect the rights of clinical trial subjects during and post covid world?

During the initial stages of the lockdown in 2020, we faced challenges in ensuring the continuity of clinical trials due to the several restrictions that were in place which led to delayed or no hospital visits, difficulties in IMP reaching patients and so on. However, this was soon resolved as stakeholders came together to collaborate in ensuring that clinical trials could continue uninterrupted without impacting the quality and integrity of clinical trial data or patient safety. Some of the routes to ensure this included: Direct to participant shipment of investigational medicinal products (IMP) so that the patient received IMP at their homes; Home nursing care visits for the administration of IMPs and collection of biological samples; Video/teleconsultation (telemedicine) of trial participants by investigators as per the protocol; and implementation of remote monitoring of patient data. Investigators worked with Ethics Committees to best manage ongoing patients and drug supplies, report SAEs, manage study visits, and so on. In the case of studies with an NCE/NBE, new patients underwent audio-video consenting of the informed consent process especially in non-COVID-19 studies. In the case of COVID-19 studies, investigators worked with ethics committees to seek the best possible way for consenting either by reading out the form and/or audio-video taping the same with the patient or their Legally Acceptable Representative or using an impartial witness. Sponsors also communicated the implementation process to the regulators.

The regulators were quick to respond in ensuring the quick implementation of digital measures to streamline processes and approvals in a pandemic world. We are hopeful that these changes will not just continue after the pandemic but that we will see an enhancement of more digital measures. Patient protection and safety are at the core of any clinical trial and that is the tenet of any clinical trial whether we are in the midst of a pandemic or not.

Going forward how beneficial will be the academic and pharmaceutical industry collaboration for clinical trials in terms of increasing participation and awareness?

The academic partnership is extremely important and intrinsic to the growth and success of clinical research which is why a few years ago, we established the Academic Consortium for Clinical Research in India (ACCRI) as part of ISCR. The ACCRI initiative was conceived to enhance clinical research in India through collaboration in areas of learning and development, capacity building and knowledge enhancement which would benefit academic institutions and researchers. As part of the initiative, we have done several types of research capacities building programs, including one in North East India, initiated a Remote Clinical Research Mentorship program aimed at junior/mid-level faculty in medical institutions who would like to build their career as a clinical researcher etc. We also have an annual best Academic Researcher Prizes for original research work across senior, junior and mid-level faculty positions for which ACCRI solicits original work from researchers in medical institutions from the length and breadth of the country.

We strongly believe that if India has to be able to develop new drugs, biologicals/vaccines, medical devices, AYUSH products etc. then we should have an equally vibrant clinical research community that can advise developers on the best clinical development plan. Hence ISCR's strategy for developing clinical researchers of the future is with an aim to contribute to drug development for the country for diseases that have unmet medical needs. The collaboration between academia and industry, as the pandemic too has shown, is highly synergistic and mutually beneficial to both.

Due to the pandemic, clinical trials have shifted to remote operations. How, do you think, we have fared upon the reliance on digital technologies? And what are the future opportunities for digital adoption?

The pandemic has not just catalysed the implementation of digital technology in clinical trials but also demonstrated their efficiency in ensuring shorter timelines and greater reliability of data without compromising on patient safety. Stakeholders across the spectrum were also quick to implement digital interventions be it the regulators, ethics committees, investigators or sites. Digital technologies that leverage algorithms, data science, and health information can play a substantial role in drug development by reducing timelines for approvals and ensuring better collaboration, thus enabling institutions to bring drugs to the market faster. However, incorporating technology in clinical research requires a steep learning curve by investigators, sponsors, participants, and other stakeholders. As we move into the second half of 2021, we must make transformative use of digital platforms for better utilization of resources and building capabilities.

What are your views on the approval of the vaccine taking place in India, particularly the fast-tracking of approvals for foreign vaccines?

A greater need for immunisation and protection has never been felt as much as during the pandemic. The world has watched as scientists, medics and clinical researchers from the industry, academia and research institutes collaborated and created new pathways to expedite the clinical development of vaccines that will help save lives and end the pandemic. We now need to ensure better and faster access to vaccines, while also focusing on how we can use learnings from vaccine development during the pandemic to advance the development of vaccines for other diseases. Fair and equitable access to immunisation, globally, is vital as it is a key element of primary health care and brings us closer to a healthier world. Bringing safe and effective COVID-19 vaccines to India required bridging clinical studies in compliance with local regulations. As there are several vaccines that have been developed in the west that have Emergency Use Authorization (EUA) based on the interim Phase III data, it becomes easy for India, being a part of the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) deliberations, to provide the possibility of EUA for vaccines which have EUA in major ICH countries. The government has shown flexibility in its approach of accepting efficacy and safety data generated till date globally, and then following it up with a parallel local bridging study. The local bridging study as well as the proposed initial 100 beneficiary safety monitoring during the rollout of the vaccine program with any foreign vaccine will allow the collection of safety and effectiveness data in Indian participants.

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