

Strategies to conduct clinical trials effectively in Covid-19 Era

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Clinimed organises webinar in association with ISCR

The Webinar on “Strategies to Conduct Clinical Trials effectively in Covid-19 era” organized by CliniMed LifeSciences Pvt. Ltd., Kolkata in association with Indian Society for Clinical Research (ISCR) and Peerless Hospital, Kolkata as knowledge partners and BioSpectrum as media partner, was held at 3 pm on June 6, 2020.

Around 500 plus participants attended this informative webinar amongst 1000 plus registrants for this webinar. “We got lot of appreciations from many research enthusiasts from the different parts of our country as well as from abroad saying it was really a timely webinar and informative one” said Mr. Snehendu Konar, Business Development Manager of CliniMed LifeSciences, organizer of this event.

The event was moderated by Dr. Subhroyoti Bhowmick, Clinical Director, Research and Academics, Peerless Hospital, Kolkata and he introduced all of our distinguished panelists with their short bio -sketch.

In the opening remarks, Dr. V. G. Somani, Drug Controller General of India (DCGI) stated the significance of artificial intelligence with risk benefits as one of the most important strategies of conducting clinical research during Covid-19 pandemic. “We have to take advantage of such validated technologies to collect data and analysis purposes to avoid physical visits” said Dr. Somani. He clearly differentiated what should be the acceptability for routine and that of pandemic situation.

Dr. Roli Mathur, head of ICMR Bioethics Unit pointed out that we should follow the strategies like virtual meeting, e-documents, e-consent, e-EC in such constraint environment. “ICMR is planning for enabling all EC committee awareness and they have enabled FAQs and forms in their website” said Dr. Roli Mathur. She also opined, “central EC can do evaluations and monitoring can be done by local EC.”

Dr. Sanis Davis, General Secretary of ISCR emphasized on how to ensure patient safety and sensitized ethics committee (EC) can support large number of studies.

According to Ms. Suneela Thatte, VP and Head, R&D Solutions, IQVIA India, the biggest challenge is to be responsible for

patient safety and maintaining health status. Some mechanisms should be there to maintain their safety. IP supply is going to be a long-term challenge- how do we bring the entire focus on handling pandemic for clinical trials research and how can we bring them back on clinical research. We need to make sure we provide tools and techniques to fulfil administrative and logistic requirements. We need to adopt virtual clinical trials in a way where patient safety is not being compromised. Remote working should be done for not only EC but for all possible committee.

Mr. Anirban Roy Chowdhury, Co-Director, CDSA, THSTI, DBT, Govt. of India spoke about the statistical approach of clinical trial where data collection method for data analysis and interpretation results become very important factors keeping scientific integrity.

Dr. Alben Sigamani, Group Head, Dept. of Clinical Research, Narayana Health shared his insights and thoughts on telephonic conversation adoption for which ICMR has released the new guidelines for follow up. We need to plan the entire phase in one period format just to see what happens amidst this COVID era.

Dr. Soma Mukhopadhaya explained the challenges of conducting clinical trial at sites. She told that the communication is the basic key. At site, SMO should arrange meeting their staff twice a week to boost them mentally up for having clear idea to attend patients, how to use precautionary measures. She appealed to the sponsors or CROs to provide protective gears like PPE kits for the frontline research staff. SMO is encouraging the sites or hospitals to conduct COVID tests before enrolling the patients for clinical trials.

Dr. Bhowmick, the moderator, then set the tone for discussion by asking the panelists the questions came from attendees via mail and Q&A session of the webinar. After this, all the panelists answered the participants' queries and the webinar concluded with the vote of thanks given by the moderator and the organizer of this webinar.