



Report of ISCR – Regulatory Council Workshop conducted in collaboration with Indraprastha Apollo Hospital, New Delhi, on 30th Nov 2018

ISCR Regulatory council in collaboration with Indraprastha Apollo Hospital conducted a one day workshop on “Exploring future trends in clinical research” at Indraprastha Apollo Hospital on 30th Nov 2018, from 0900 am to 0600 pm. Around 45 participants registered for the workshop. Agenda of the workshop is enclosed as Annexure A.



Inaugural Ceremony

Inauguration of the workshop was done by Maj. Gen. Dr Jagtar Singh, Director Medical Services, Apollo Hospital. Dr Singh welcomed the participants and wished them all the best for a day long learning event. He shared that Apollo and ISCR both organizations promote conduct of ethical clinical research.

Speakers' Sessions

Subsequently, various topics like Stem cell research, Risk based monitoring, New Drugs and Clinical Trial draft regulations, challenges faced by Ethics Committees etc. were covered by eminent speakers - Dr Pooja Sharma, Dr Prabhu Mishra, Dr Vinay Ranjan, Ms. Alka Singh, Mr Tarun Pandotra.



Participants listening to speakers



Visualizing future clinical trials

Participants enjoyed the break out session pretty much in which the participants were divided in 3 groups and were asked to brain-storm on how future clinical trials will look like in 2025 and beyond. Each group presented outcome of their group discussions and shared their thoughts with the other groups. All groups were evaluated by experts and winners were felicitated by Deputy Drugs Controller Sh. A K Pradhan.





Panelists: Dr P K Das, Mr. Arun Sundariyal, Sh A K Pradhan, Dr Y K Gupta, Dr Pooja Sharma, Dr Vaishna Narang, Dr Sandeep Upadhyaya

Panel Discussion

Theme of the Panel Discussion: “Strengthening trust between various stakeholders of clinical research”

The Panel was well represented by an expert member from each of the key stakeholder group involved in Clinical Research. The main aim of the discussion was to bring forth to the table the pertinent points regarding how the trust deficit between the different stakeholders involved in the entire cycle of a clinical trial can be addressed and what are some of the important actionable that can be taken.

Questions were raised to the panelists regarding empowering ethics committees, factors considered by global sponsors while selecting India as country of choice to conduct a clinical trial, how the current environment of India is perceived by the global companies, how can the conduct of SEC meetings and their overall functioning be made more harmonized across therapeutic areas, the role played by media towards reporting of CTs and plans of the government to engage with this set of stakeholders, how PIs can ensure effective monitoring of their sites during the conduct of a clinical trial and what techniques can be practically used to improve the Informed Consent process at the sites.

There was a very energized and a knowledgeable exchange of thoughts and opinions between the panelists for each of the questions raised. Some very practical and useful insights were brought up “Food for Thought” to planning the way forward. The overall take away message from the informative discussion was that each and every member, belonging to any stakeholder group from all across the industry has a unique role to play towards working TOGETHER to bridge the trust deficit. Each and everyone needs to strive towards absolute quality in all of their activities and take accountability of the task assigned to them, *Only Together We Can Build a Better Tomorrow of Clinical Research in India.*



Group photo – Participants, Speakers, Local Organizing Committee

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Annexure A – Workshop Agenda

ISCR Workshop “EXPLORING FUTURE TRENDS IN CLINICAL RESEARCH” 30 th Nov 2018, Indraprastha Apollo Hospital, Sarita Vihar, New Delhi		
AGENDA		
Time [hrs]	Discussion Topic	Speaker(s)
0900 – 0930	Registration & Tea	
0930 – 0945	Welcome & Inaugural address	Director, Apollo Hospital / Organizing Committee
0945 - 1015	Risk Based Monitoring in clinical trials – New trends	Ms. Alka Singh , Centralized Monitoring Lead, Clinical Operations, IQVIA
1015 - 1045	Overcoming challenges faced by Ethics Committees [ECs]	Dr. Pooja Sharma , Senior Scientist and Head, Medanta Institute of Education and Research, Medanta The Medicity Hospital
1045 - 1100	Tea & Networking Break	
1100 - 1130	Clinical Trials with Medical Devices	Dr. Vinay Rajan , Regional Clinical Leader, Medtronic
1130-1200	Advances in Stem Cell Clinical Research	Dr. Prabhu Mishra , CEO - StemGenn Therapeutics, President -StemMax Research
1200 - 1300	Break out session – Visualizing the future of clinical trials in India [Poster / Chart activity]	Participation – All participants Facilitator – Workshop Organizing Committee
1300 – 1400	Lunch Break	
1400 - 1445	New Drugs and Clinical Trial Rules [2018] – way forward for Clinical Trials in India	Tarun Pandotra - Founder & Director, Global Regulatory & Consumer Insights
1445 - 1530	Raising the quality bar at the Investigator level [Preparing sites for clinical trials of future]	Dr. Y. K. Gupta , Principal Adviser (Projects), Translational Health Science & Technology Institute (THSTI), Department of Biotechnology, Govt of India
1530 - 1545	Tea Break	
1545 - 1700	Panel Discussion: Strengthening trust between various stakeholders of clinical research	Sh. A K Pradhan - Deputy Drugs Controller (India) Dr. Y. K. Gupta - Principal Adviser (Projects), Translational Health Science & Technology Institute (THSTI), Department of Biotechnology, Govt of India Dr. Pooja Sharma - Senior Scientist and Head, Medanta Institute of Education and Research, Medanta The Medicity Hospital Arun Sundriyal - Sr. Director Clinical management, Area Head Central & North Asia, PPD Dr. P.K.Das – Senior Medical Oncologist, Haemato- Oncologist and Academic Coordinator, Dept. of medical oncology at Apollo Cancer Institute, New Delhi. Dr. Vaishna Narang - Professor of Linguistics, Former Dean, School of Language, Literature and Culture Studies, JNU, Member of Ethics Committee and Stem cell Committee.
1700 - 1730	Wrap-up and Conclusions	Zonal organizing team