Indian Society for Clinical Research

Announces a One-Day workshop

REFORMATIONS AND FUTURE READINESS: CLINICAL TRIAL REGULATIONS

Schedule:

Date	Time	Venue
10-Dec-16	8:30 am – 6:00 pm	**Kolkata- Novotel,** Rajarhat, Action Area 1C, Newtown, Kolkata - 700156

INTRODUCTION: This one day workshop designed to present & clarify the evolving regulatory landscape especially over the last one year. Topics mentioned in this draft flyer will make this interface useful and interesting for professionals with Clinical Research.

SCOPE: To provide an overview of the recent developments governing the process of filing, review and approval of Clinical Trial applications including relevant recent updates.

TARGET AUDIENCE: Regulatory & Clinical Research Associates of Sponsors & CROs, Investigator Sites and Ethics Committees

Agenda		
Time	**Topic**	**Speaker**
8:30 to 9:00 am	Registration & Tea	
9:00 to 9:15 am	Welcome	Ms. Shashwati Devsharma (ISCR Reg Council Chairperson) Dr. Sauren Das (Excel Life Sciences) Ms. Gargi Roychowdhury Dr. Gaurav Mathur (QuintilesIMS)
9:15 to 10:00 am	2016 Regulations changes /updates	Dr. Sauren Das (Excel Life Sciences)
10:00 to 11:00 am	CT online submissions	Ms. Rubina Bose (CDSCO, New Delhi)
11:00 to 11:30 am	**TEA BREAK**	
11:30 to 12:30 pm	Best practices in managing global trials by EC and Investigators and SEC meetings Experts view and industry view	Dr. Shoibal Mukherjee (Industry) Ms. Shashwati Devsharma (Industry – Pfizer) Dr. Santanu Tripathi (PI - Sch of Tropical Med) Dr. Chanchal Goswami (PI - Apollo) Dr Raja Dhar(PI - Fortis) / Dr. Suparna Chatterjee (IPGMER) Dr. Avijit Hazra (EC - IPGMER) Moderator - Mr. Anirban Roychowdhury (Industry - Merck)
12:30 to 1:00 pm	Interview of EC members	Dr. Avijit Hazra (EC - IPGMER) Dr. Sukumar Mukherjee (CMRI) Moderator – Dr. Sauren Das (Excel Life Sciences)
1:00 to 1:45 pm	**LUNCH BREAK**	
1:45 to 2:00 pm	Video clip of international stakeholders perspective	

2:00 to 3:00 pm	Break out session: Regulatory feasibility of a new CT protocol	Team activity for the participants (ISCR Regulatory Council Member)
3.15 – 3:30 pm	**TEA BREAK**	
3:30 to 5:30 pm	Panel Discussion: Regulation Changes and future readiness: Representatives from- • Industry • Regulatory • EC • Investigator • SEC	Ms. Rubina Bose (Regulator – CDSCO, New Delhi) Dr. Sauren Das (Industry – Excel Life Sciences) Dr. Santanu Tripathy (PI - Sch of Tropical Med) Dr. Chanchal Goswami (PI - Apollo) Dr Raja Dhar (PI - Fortis) Dr. Avijit Hazra (EC - IPGMER) Moderator – Dr. Shoibal Mukherjee (Industry)
5.30 – 5:45 pm	Wrap Up and Conclusions	Dr. Sauren Das / Ms. Gargi Roychowdhury

Registration details:

No. of Participants: **50**
Delegate Fee:
For ISCR Members – Rs 3000/-
For Non-Members – Rs 3500/-
Academia/Students – Rs.1500/-

Mode of Payment: 1) Online 2) Cheque/DD

Online registration (compulsory): - http://www.iscr.org/events-registration/
Online Payment link: http://www.iscr.org/payment-events-workshops/
Cheque/DD: Payable at Mumbai should be made in favor of **"Indian Society for Clinical Research"**
Mailed to us at: ISCR Secretariat, C/o Pfizer Centre, TheCapital,1802,18thFloor, PlotNo.C-70, 'G'Block,BandraKurlaComplex, Bandra (E), Mumbai- 400051

For any query please feel free to write to info@iscr.org or call on **+91-8454827775**