



Indian Society for Clinical Research Announces a One-Day workshop

EVOLVING REGULATORY LANDSCAPE: OPPORTUNITIES & CHALLENGES!!

Schedule:

Date	Time	Venue
30-Oct-15	8:30 am – 6:00 pm	Mumbai – Hotel Orchid , 70C, Nehru Road, Near Sahara Hotel, Vile Parle East, Mumbai
27-Nov-15	8:30 am – 6:00 pm	Bangalore –Goldfinch Hotel , # 32/3, Crescent Road, Off High Grounds, Race Course Road, Bengaluru – 560 001
04-Dec-15	8:30 am – 6:00 pm	Delhi – India Habitat Centre , Lodhi Road, Near Airforce Bal Bharati School, New Delhi, Delhi 110003, India

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

Agenda		
Time	Topic	Speaker
8:30 to 9:00 am	Registration & Tea	
9:00 to 9:15 am	Welcome	West Zone organizing team
9:15 to 10:00 am	How to build compile high quality regulatory submissions - best practices	Yasmin Shenoy (Sanofi)
10:00 to 11:15 am	CTAs: Recent changes - application process - review and approval process	Paresh Tipare (PPD)
11:15 to 11:45 am	TEA BREAK	
11:45 to 12:15 pm	How to optimize clinical operations and regulatory affairs collaboration	Murugananthan K / Amita Bhave(Novartis)
12:15 to 12:45 pm	Accreditation of Investigators, Sites and ECs: updates	Dr. Madhuri Jadhav (ADAMAS Consulting)
12:45 to 1:15 pm	Compensation and safety - Journey from 2013 to 2015	Dr. Partha Gokhale (Boehringer)
1:15 to 2:00 pm	LUNCH BREAK	
2:00 to 2:45 pm	Career Development – Learning from seniors	Dr. Arun Bhatt (President, ClinInvent), Dr. Suresh Menon (Novartis) (Facilitator- Girish Parhate (Bayer))
2:45 to 3:15 pm	D&C amendment bill and rules - updates	Kedar Suvarnapathaki (Boehringer)
3.15 – 3:45 pm	TEA BREAK	
3:45 to 5:45 pm	Panel Discussion: SEC functioning - Investigator - SEC expert - Regulator Industry representative	Investigators- Dr C S Pramesh (TMH) SEC - Dr. Banavali (TMH) Industry- Dr. Menon (Novartis) Regulators- TBC (Facilitator- Amita Bhave (Novartis))
5.45 – 6.00 pm	Wrap Up and Conclusions	West Zone organizing team

Registration details:

No. of Participants: 50

Delegate Fee:

For ISCR Members – Rs 2500/-

For Non-Members – Rs 3000/-

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

Online registration (compulsory): - http://www.iscr.org/events_MemberRegistration.aspx

Online Payment link: <http://www.iscr.org/Events.aspx>

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, Patel Estate, S.V. Road, Jogeshwari (W),
Mumbai – 400 102

For any query please feel free to write to info@iscr.org org call on **+91-22- 6693 2028/2440**