



Indian Society for Clinical Research

Regulatory Council Announces a One-Day workshop

REFORMATIONS AND FUTURE READINESS: CLINICAL TRIAL REGULATIONS

Schedule:

Date	Time	Venue
18-Nov -16	8:30 am – 6:00 pm	Mumbai – Hotel Orchid, 70C, Nehru Road, Near Sahara Hotel, Vile Parle East, Mumbai

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, Pharmacy and Clinical Research students

**ISCR Workshop: REFORMATIONS AND FUTURE READINESS:
CLINICAL TRIAL REGULATIONS**

Time	Topic	Speaker
8:30 to 9:00 am	Registration & Tea	-
9:00 to 9:15 am	Welcome	Regulatory council Chair Dr. Shashwati Devsharma, Pfizer
9:15 to 10:00 am	Recent regulatory reforms for clinical research	Ms. Yasmin Shenoy, Sanofi
10:00 to 11:00 am	Break out session: Regulatory feasibility of a new CT protocol in today's context	West zone organizing team
11:00 to 11:30 am	TEA BREAK	
11.30 to 11.45 pm	International stakeholders perspectives on clinical research regulatory reforms in India	Video clip
11.45 to 12.45 pm	CDSCO new initiatives - CT online submissions	Ms. Anagha Padhye, Novartis
12.45 to 1.30 pm	LUNCH BREAK	
1:30 to 2:00 pm	Insights into revised EC roles and responsibilities	Dr Renuka Munshi, BYL Nair Hospital, Ms.Shehnaz Vakharia , ADAMAS
2:00 to 3.00 pm	Best Practices in SEC meeting: Views from SEC experts and Industry experts	SEC expert- Dr Shripad Banavali , Prof and Head, Dept.of Medical and Clinical Oncology, TATA Memorial Hospital Industry Expert- Dr Chirag Trivedi, Sanofi

3.00 – 3:30 pm	TEA BREAK	
3:30 to 5:30 pm	<p>Panel Discussion:</p> <p>Regulation updates and future readiness:</p> <p>Panelists from-</p> <ul style="list-style-type: none"> • Regulator • SEC panel expert • Ethics Committee • Investigator • Industry 	<p>Moderator: Ms. Amita Bhave - Novartis Co-chair Regulatory council</p> <p>Regulator – Ms.A.Visala Dy.DCGI, CDSCO</p> <p>SEC expert- Dr Shripad Banavali , Dept.of Medical and Clinical Oncology, TATA Memorial Hospital</p> <p>EC- Dr Renuka Munshi, BYL Nair Hospital</p> <p>Investigator- Dr Jyotsna Oak, Kokilaben Hospital</p> <p>Industry- Dr Suresh Menon, Novartis</p>
5.30 – 5:45 pm	Wrap Up and Conclusions	Zonal organizing team

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

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