



INDIAN SOCIETY FOR CLINICAL RESEARCH

Regulatory Council

in collaboration with

Tata Memorial Hospital, Mumbai

presents

One-Day Workshop on “New Regulations to Further Strengthen Clinical Research in India”

03rd October 2019 (Thursday)

At

Auditorium of Tata Memorial Hospital

Dr Ernest Borges Rd, Parel, Mumbai

Agenda		
Time	Topic	Speaker
09:30 to 10:00	Registration & Tea	
10:00 to 10:30	Welcome & Introduction to ISCR	Representatives from ISCR Reg Council and Dr. Sripad Banavali, Director/ Dean Academics, Prof. Dept of Medical and Pediatric Oncology, Tata Memorial Centre
10:30 to 1:00	New Drugs and Clinical Trials Rules, 2019	
10:30 to 11:15	New CT Rules – Overview, Highlights and Impact Q-A	Dr Rubina Bose, Deputy Drugs Controller, CDSCO West Zone, Mumbai
11:15 to 11:30	TEA BREAK	
11:30 to 1:00	New CT Rules – Discussion from stakeholder’s perspective: <ul style="list-style-type: none"> Regulator Sponsor-CRO Investigator Academia Ethics Committee Facilitator : Amita Bhawe, Regulatory Head, Novartis	<ul style="list-style-type: none"> Regulator - Dr Rubina Bose, CDSCO West Zone, Mumbai Sponsor- Dr Suresh Menon, Chief Scientific Officer, Novartis Investigator- Dr Sudhir Pawar, Sion Hospital & Medical College Academia – Dr Kumar Prabhash, Prof. Medical Oncology, Tata Memorial Hospital Ethics Committee – Dr Urmila Thatte, Prof and Head, Dept of Clin Pharmacol, Seth G S Medical College and KEM Hospital, Parel
13:00 to 13:30	Q&A Session	
13:30 to 14:30	LUNCH BREAK	
14:30 to 15:30	Newer Areas of Clinical Trials	
14:30 to 15:00	BA/BE studies	Dr Kiran Marthak, Director- Head Global Clinical Development, Lambda Therapeutic Research Ltd
15:00 to 15:30	Biosimilar studies	Samyuktha Ajay, Independent Consultant
15:30 to 15:45	Q&A session	
15:45 to 16:00	TEA BREAK	
16:00 to 17:30	Panel Discussion	
16:00 to 17:30	Topic: <i>CHALLENGES IN GOVERNANCE AND REGULATORY COMPLIANCE WHILE CONDUCTING CLINICAL TRIALS and REGULATORY INSPECTIONS</i> Moderator -Dr Partha Gokhale, Head Clinical Development Boehringer – Ingelheim Ltd Q&A Session	Panelists: Representatives from: <ul style="list-style-type: none"> Regulator –Dr Rubina Bose, Deputy Drugs Controller, CDSCO West Zone, Mumbai Academia –Dr Kumar Prabhash, Prof. Medical Oncology, Tata Memorial Hospital Investigator- Dr Vyankatesh Shivane, Diabetologist Ethics Committee- Dr Yashashri Shetty, Associate Professor, Dept of Pharmacology, Seth G.S. Medical College & KEM Hospital, Mumbai.
17:30 to 17:45	Wrap-up and Thank you	ISCR RC-SC Organizing Team

Registration and Payment details:

Registration fees:

Academia	Ethics Committee members and Clinical Research Coordinators	ISCR Member (For Individual & Corporate Members – AMOs)	Non-Member
Rs 1000/-	Rs 2000/-	Rs 3500/-	Rs 4500/-

All registered participants will get a “Certificate of Attendance” from ISCR

Online registration - <http://www.iscr.org/events-registration/>

Online payment - <http://www.iscr.org/payment-events-workshops/>

Offline Payment - 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 Limited, The Capital 1802, 18th Floor, Plot No. C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

For any query, please feel free to write to info@iscr.org