



INDIAN SOCIETY FOR CLINICAL RESEARCH

Regulatory Council- South Chapter

in collaboration with

HCG Hospital, Bengaluru

presents

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

27th September 2019 (Friday)

At

Auditorium, First Floor, Tower 5,

No 8, HCG Towers, P. Kalinga Rao Road, Sampangi Ram Nagar,

Bengaluru, Karnataka- 560020

Tel: 080 40206000

Agenda		
Time	Topic	Speaker
08:30 to 09:00	Registration & Tea	
09:00 to 09:30	Welcome & Introduction to ISCR	<i>Dr. B S Ajai Kumar, Chairman and CEO HCG Hospital</i> <i>Ms. Mala Srivastava, Co-founder and Managing Partner Nextvel Consulting LLP (On behalf of ISCR RC)</i>
09:30 to 13:00	New Drugs and Clinical Trials Rules, 2019	
09:30 to 10:30	New CT Rules – Overview, Highlights and Impact	<i>Dr. Nagaraj Bannur</i> <i>Regulatory Affairs & Patient Safety, India & AA FM, AstraZeneca, Bangalore</i>
10:30 to 10:45	TEA BREAK	
10:45: to 12:30	New CT Rules – Discussion from stakeholder’s perspective: <ul style="list-style-type: none"> • <i>Sponsor-CRO</i> • <i>Investigator</i> • <i>Academia</i> • <i>Ethics Committee</i> • <i>BA/BE studies</i> 	<i>Sponsor-CRO</i> <i>Mr. Sanjay Kabra -Director, Global Services Center (India), Novotech Asia Pacific CRO Investigator</i> <i>Dr Paramesh Shamanna, Diabetologist & Endocrinologist at Bangalore Diabetes Centre</i> <i>Academia</i> <i>Dr. Denis Xavier -Vice Dean (PG) Professor of Pharmacology, St. John's Medical College</i> <i>Ethics Committee</i> <i>Mr. Sudhir Patel, Chief Operation and Co-founder, Quinary Clinical Research</i> <i>BA/BE Studies</i> <i>Dr. Vasudev Shenoy General Manager</i> <i>BA/BE Services at Navitas Life Sciences</i>
12:30 to 13:00	Q&A Session	
13:00 to 14:00	LUNCH BREAK	
14:00 to 15:30	Operational Aspects of Clinical Trials	
14:00 to 14:45	Legal considerations of conducting clinical trials in India	<i>Ms. Smitha Chandrashekaraiiah, Director Legal - IQVIA</i>
14:45 to 15:30	SUGAM submissions – Tips and Tricks	<i>Dr. Nagaraj Bannur, Director –Regulatory Affairs & Patient Safety, India & AA FM, AstraZeneca, Bangalore</i>
15:30 to 15:45	TEA BREAK	
15:45 to 17:15	Panel Discussion	

15:45 to 17:15	<p>Topic:</p> <p>CHALLENGES IN GOVERNANCE AND REGULATORY COMPLIANCE WHILE CONDUCTING CLINICAL TRIALS</p> <p>Regulator Dr. Roli Mathur Scientist E NCDIR</p> <p>Academia Dr. Anuradha H V Professor & Head Department of Pharmacology at M S Ramaiah Medical College and Hospital, Bengaluru</p> <p>Sponsor/Industry Dr. Ramesh Jagannathan Associate Vice-President, Head-Clinical Development, Biocon Research Ltd. Bengaluru</p> <p>Investigator /SEC Dr. Radheshyam Naik Medical Oncologist-HCG Cancer Hospital</p> <p>Ethics Committee Dr. Ananya Chakraborty Professor and Head Department of Pharmacology VYDEHI INSTITUTE OF MEDICAL SCIENCES & RESEARCH</p> <p>Ms. Manjulika Vaz Lecturer Health and Humanities St John's Research</p> <p>Moderator Dr. Surinder Kher Advisor BioQuest Solutions Pvt Ltd</p> <p>Q&A Session</p>	<p>Panelists:</p> <p><i>Representatives from:</i></p> <ul style="list-style-type: none"> • <i>Regulator</i> • <i>SEC member TBD</i> • <i>Academia</i> • <i>Investigator TBD</i> • <i>Ethics Committee</i> • <i>Industry (Pharma, BA/BE, CRO / SMO/ TBD)</i>
17:15 to 17:30	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/-

Seat Limit - We have limited seats. Registration will close once the seat limit is reached.

All registered participants will get a “Certificate of Participation” 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