



**INDIAN SOCIETY FOR CLINICAL RESEARCH**

**Regulatory Council**

**In collaboration with**

**Department of Clinical Pharmacology,  
Seth G.S. Medical College, Mumbai**

**Present a**

**One-Day workshop on**

**“EXPLORING FUTURE TRENDS  
IN CLINICAL RESEARCH”**

**1st November 2018**

**Dr. Jivraj Mehta Lecture Theatre (MLT)**

**Seth G S Medical College and KEM Hospital, Parel, Mumbai 400012**

Agenda		
Time	Topic	Speaker
09:00 to 09:30	Registration & Tea	
09:30 to 09:45	Welcome	<b>ISCR representative and Dr Urmila Thatte</b>
09:45 to 10:15	Raising the quality bar at the investigator level	<b>Dr Nithya Gogtay,</b> Additional Professor, Clinical Pharmacology, Seth G.S. Medical College & KEM Hospital, Mumbai
10.15 to 10.30	GCP Compliance Trends	<b>Shehnaz Vakharia,</b> Managing Director, ADAMAS Consulting
10:30 to 11:00	Newer trends – Risk Based Monitoring	<b>Muruganathan K,</b> Country Monitoring Head, Global Development Operations, Novartis Healthcare Pvt Ltd
11:00 to 11:15	Break	
11:15 to 11:45	Overcoming challenges faced by Ethics Committees [ECs]	<b>Dr Yashashri Shetty,</b> Associate Professor, Dept of Pharmacology, Seth G.S. Medical College & KEM Hospital, Mumbai. Joint member secy of KEM Hospital EC and Member of Tata Hospital EC
11:45 to 12:45	Case Study Quiz in Break out session	<b>Organising Committee</b>
12:45 to 13:45	LUNCH BREAK	
13:45 to 14:15	Expectations- upcoming revised D&C Rules	<b>CDSCO official TBC</b>
14:15 to 15:30	Need to know more of Clinical research  a) Stem cells  b) Real World Evidence (RWE)	<b>a) Dr Pawan Gupta,</b> Vice President, Medical and Regulatory Affairs, Stempeutics Research, Bangalore  <b>b) Mahendra Rai, Iqvia</b> Head, Real World Insights (RWI) - South Asia at IQVIA
15:30 to 15:45	TEA BREAK	
15:45 to 17:15	Panel Discussion: Strengthening trust between various stakeholders of clinical research	<b>CDSCO official TBC</b>  <b>Investigator: Dr Sneha Limaye</b> Head of Dept of Clinical Trials & Respiratory Research Network at Chest Research Foundation (CRF) Pune  <b>EC/ SEC: Dr Urmila Thatte,</b> Prof & Head Department of Clinical Pharmacology, Seth G S Medical College & KEM Hospital  <b>Sponsor: Dr Chirag Trivedi,</b> ISCR president; Director and Head of Clinical Study Unit (CSU) Sanofi India  <b>Moderator: Amita Bhave ,</b> Head Regulatory Affairs, Global Drug Development India, Novartis Healthcare Private Ltd
17:15 to 17:30	Wrap-up and Thank you	<b>ISCR Organizing Team and Dr Urmila Thatte</b>

