



## Indian Society for Clinical Research Announces a One-Day workshop

### REFORMATIONS AND FUTURE READINESS: CLINICAL TRIAL REGULATIONS

#### Schedule:

Date	Time	Venue
2-Dec-16	8:30 am – 6:00 pm	<b>Bangalore –Goldfinch Hotel</b> , # 32/3, Crescent Road, Off High Grounds, Race Course Road, Bengaluru – 560 001

**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, Investigator Sites and Ethics Committees

<b>Agenda</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
8:30 to 9:00 am	Registration & Tea	
9:00 to 9:15 am	Welcome	Organizing team: Dr. Ramesh Jagannathan (Novo Nordisk) / Dr. Gaurav Mathur (QuintilesIMS) / Mr. Jayasheel Gangaiah (Alcon) / Ms. Thanuja Naidu (PharmOlam)
9:15 to 09:45 am	2016 Regulations changes /updates	Mr. Jayasheel Gangaiah (Alcon)
09:45 to 11:00 am	CT online submissions	Ms. Sneha Gupta (Sanofi)
	<b>TEA BREAK</b>	
11:30 to 12:30 pm	Best practices in managing SEC meetings Experts view and industry view	Moderator: Gaurav Mathur (QuintilesIMS) SEC Member: TBD (Dr Alok Shrivastava – CMC, Vellore) Academia: Dr. Prem Pais Industry Expert: Dr. Ramesh Jagannathan
12:30 to 1:15 pm	Interview of EC members	Moderator – Dr. Srikanth K (Coimbatore)  EC Members: Dr. K. Laxminarayana Bairy (Manipal) Dr. Jyothi Idiculla (St. John's Hospital) Dr. Raghavendra Rao (HCG)
1:15 to 2:00 pm	<b>LUNCH BREAK</b>	
2:00 to 2:15 pm	Video clip of international stakeholders perspective	
2:15 to 3:30 pm	Break out session: Regulatory feasibility of a new CT protocol	Team activity for the participants (Dr. Srikanth K. / Jayasheel Gangaiah)
3.30 – 3:45 pm	<b>TEA BREAK</b>	

3:45 to 5:15 pm	<p>Panel Discussion: Regulation Changes and future readiness: Representatives from-</p> <ul style="list-style-type: none"> <li>• Industry</li> <li>• Regulatory</li> <li>• EC</li> <li>• Investigator</li> <li>• SEC</li> </ul>	<p>Moderator – Dr. Ramesh Jagannathan (Novo Nordisk)</p> <p>Regulatory: Mr. Jayant Kumar (CDSCO official – to be confirmed)</p> <p>SEC member: TBD (Dr Alok Shrivastava – CMC, Vellore)</p> <p>Investigator: Dr Srikanth K. (Coimbatore)</p> <p>Academia: Dr. Prem Pais</p> <p>EC Members: Dr. K. Laxminarayana Bairy (Manipal EC); Dr. Jyothi Idiculla (St. John’s Hospital) Dr. Raghavendra Rao (HCG)</p> <p>Industry: Dr. Gaurav Mathur (QuintileIMS) / Mr. Jayasheel Gangaiah (Alcon)</p>
5.15 – 5:30 pm	Wrap Up and Conclusions	Dr. Ramesh Jagannathan (Organizing Committee)

### 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

**For any query please feel free to write to [info@iscr.org](mailto:info@iscr.org) or call on [+91-8454827775](tel:+91-8454827775)**