



**Indian Society for Clinical Research in collaboration with St. John's Medical College and Research Institute  
Announces a One-Day Program**

***'Accreditation for Clinical Research:  
Awareness and Expectations'***

**Program Partner:**

**ADAMAS**

**Date: Saturday, October 10, 2015**

**Timing: 09:00 am – 5:00 pm**

**Venue: Pope Paul Auditorium, St. John's Medical College Research Institute Campus, Opposite BDA complex, Koramangala, Bengaluru- 560034**

**INTRODUCTION:**

Very soon Quality Accreditation, a proposal initiated by the Health Ministry, will become mandatory for new clinical studies in the country. Investigator Sites (Institutions, Hospitals, etc.) Ethics Committees (ECs) and Investigators would have to seek accreditation from the Quality Council of India (QCI) before being able to seek approval from the drug regulator for conducting/overseeing a clinical study. For ongoing trials, it may not be made mandatory immediately, but these will also be brought under the accreditation fold eventually.

The Quality Council of India that offers quality certification to hospitals, clinics, blood banks, wellness centres, and dental clinics, is firming up standards that Investigator Sites, ECs and Investigators conducting such clinical studies need to maintain to get accreditation.

This one-day program aims to generate awareness about the standards and to decipher the expectations while gearing up to comply with them. It would be important to understand the accreditation process, its impact, challenges, actions for each stake holder and the industry responsibilities.

**TARGET AUDIENCE:**

Investigators, Site staff, Ethics Committee members, Senior level members of the clinical research industry (Project Managers, Senior Project Manager, Head of Clinical Operations, Clinical Operations Director, Head of Quality Assurance, etc.),

## AGENDA

Time	Session	Speaker
09:00 am – 09:45 am	Registration	
9.45 am to 10.00 am	Inauguration & welcome address	Dr. George D' Souza (Prof & Head, Chest Medicine, St. John's Medical College; Dean, St. John's Research Institute)
10.00 am – 10.10 am	Overview and Scope	Dr. Arun Bhatt (President, ClinInvent & Executive Committee Member, ISCR)
10.10 am – 10.40 am	Accreditation for Clinical Research: A Paradigm Shift for India	Dr. Arun Bhatt
10.40 am – 11.30 am	Site Accreditation	Ms. Chandana Pal (Chief Administrator-Clinical Research Course, Apollo Research & Innovations)
11.30 am – 11.50 am	<b>TEA/COFFEE BREAK</b>	
11.50 am – 12.40 pm	Investigator Accreditation: Practical Application	Dr. Srikanth Krishnamurthy (Sr. Consultant-Respiratory Medicine)
12.40 pm – 01.30pm	Ethics Committee Accreditation	Dr. P. Usharani (Addtl. Prof. & Head, Pharmacology, & Ethics Committee Member , Nizam's Inst. of Medical Sciences)
01.30 pm – 2.15 pm	<b>LUNCH BREAK</b>	
02.15 pm – 02.45 pm	Academia and Industry collaboration in Clinical Research – Challenges and Opportunities	Dr. Denis Xavier (Prof & Head, Pharmacology, St. John's Medical College)
02.45 pm – 03.00 pm	ISCR Overview	Dr. Ramesh Jagannathan (Medical Director, Novo Nordisk India & EC Member, ISCR)
03.00 pm – 04.00 pm	<p><b><u>Accreditation - Deciphering the Impact, Challenges and Action Items</u></b></p> <p><b>Panel Discussion:</b> Dr. Prem Pais (St. John's), Dr. Arun Bhatt, Dr. Usharani, Dr Srikanth K., Ms. Chandana Pal, Dr. Gaurav Mathur (Quintiles)</p> <p><b>Moderator:</b> Dr. Madhuri Jadhav (Sr. Auditor-ADAMAS Clinical Quality Consulting)</p> <ul style="list-style-type: none"> <li>• Ethics Committee Perspective</li> <li>• Principal Investigator Perspective</li> <li>• Hospital/Site Perspective</li> <li>• Industry Perspective</li> <li>• Regulatory Perspective</li> </ul>	
04.00 pm – 04.15 pm	Q & A and Wrap Up	
04.15 pm – 05.00 pm	<b>TEA/COFFEE and Departures</b>	

**Registration details:**

**No. of Participants: 50**

**Delegate Fee:**

- For Investigators/Site staff/EC members/Academia – Rs. 1000
- For industry participants:
  - ✓ For ISCR Members - Rs. 1500/- per person
  - ✓ For ISCR Non-members – Rs. 2000/-

**Last date of registration & Payment is 7<sup>th</sup> October, 2015**

**Mode of Payment:** 1) Online 2) Cheque/DD

**Online registration (compulsory):** - [http://www.iscr.org/events\\_MemberRegistration.aspx](http://www.iscr.org/events_MemberRegistration.aspx)

**Online Payment link:** <http://www.iscr.org/Events.aspx>

**Cheque/DD:** Payable at Mumbai should be made in favor of “Indian Society for Clinical Research”