



Indian Society for Clinical Research
Announces a One-Day Program
***'Accreditation for Clinical Research:
Awareness and Expectations'***

Program Partner:



Date: August 22, 2015 (Saturday)

Timing: 09:30 am – 05:00 pm

Venue: India International Center, LECTURE ROOM - II (BASEMENT),

40, Max Mueller Marg, New Delhi – 110003, Telephone Number: 011 - 24619431

INTRODUCTION:

Very soon Quality Accreditation, a proposal initiated by the Health Ministry, will become mandatory for new clinical studies in the country. Investigator Sites (Institution, 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	Facilitators
09:30 am – 10:00 am	Registration	
10.00 am – 10.15 am	Introduction-Overview & Scope	Mr. Anil Seth (Hon. General Secretary, ISCR)
10.15 am – 10.45 am	Accreditation for Clinical Research: A Paradigm Shift for India	Prof. Ranjit Roy Chaudhury
10.45 am – 11.45 am	Site Accreditations	Dr. Ashish Rastogi (Asst. Director Clinical Operations, Excel Life Sciences Pvt. Ltd)
11.45 am – 12.45 pm	Investigator Accreditation	Dr. Sudhakar Bangera (Program Director, Clinical Development Services Agency)
12:45 pm – 1:45 pm	LUNCH	
01.45 pm – 02.15pm	Ethics Committee Accreditation	Dr. P Usharani (Additional Professor and Head, Nizam's Institute of Medical Sciences)
02.15 pm – 02.45 pm	ISCR outreach	Mr. Anirban Roy Chowdhury, Dr. Ritika Bajaj (Associate director GCO, Biogenidec)
02.45 pm – 03.15 pm	TEA BREAK	
03.15 pm – 04.15 pm	<p>Panel Discussion: Accreditation-Impact Challenge and Action Items</p> <p>Panelists : Dr. Y K Gupta, Dr. VG. Somani , Dr. KK Kalra (NABH), Dr. Pooja Sharma (Medanta) Dr. Vishal Goyal (DNDI), Dr. Seema Pai (Daiichi Sankyo), Dr. Usharani (NIMS)</p> <p>Moderator : Dr. Chitra Bargaje (Adamas)</p> <ul style="list-style-type: none"> • Regulatory Perspective • Industry Perspective • Ethics Committee Perspective • Principal Investigator Perspective 	
04.15 pm – 04.45 pm	Q & A and Wrap Up	

Registration details:

No. of Participants: 50

Delegate Fee: For Investigators/Site staff/EC members/Academia – Rs. 1000

For ISCR Members - Rs. 1500/- per person For ISCR Non-members – Rs. 2000/-

Last date of registration & Payment extended to 19th August, 2015

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

Online registration (compulsory): - 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”

Mailed to us at: ISCR Secretariat, C/o Pfizer Centre, Patel Estate, S.V. Road, Jogeshwari (W), Mumbai – 400 102 **Email:** info@iscr.org **Tel.:** +91-22- 6693 2028/2440