



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

Program Partner:

ADAMAS

Date: June 6, 2015 (Saturday)

Timing: 09:30 am – 05:30 pm

**Venue: Hotel Orchid, 'Chancery I', 70C, Nehru Road, Near Sahara Hotel (Domestic Airport),
Vile Parle East, Mumbai – 400099 (Tel: +91-22-2616 4040)**

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:

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	Facilitator
09:30 am – 10:00 am	Registration and Breakfast	
10.00 am – 10.10 am	Overview and Scope	Ashwani Pandita DGM and Head Quality Management & Training Global Clinical Research Operations Glenmark Pharmaceuticals Limited
10.10 am – 10.45 am	Accreditation for Clinical Research: A Paradigm Shift for India	Dr Arun Bhatt President-ClinInvent Research Pvt Ltd
10.45 am – 11.45 am	Site Accreditation	Chandana Pal Chief Administrator-Clinical Research Course, Apollo
11.45 am – 12.45 pm	Investigator Accreditation: Practical Application	Dr Sadhna Joglekar Vice President & Area Medical Director Asia Developing Countries, GlaxoSmithKline
12:45 pm – 1:45 pm	LUNCH BREAK	
01.45 pm – 02.45pm	Ethics Committee Accreditation	Dr Rakhi Tripathi Associate Professor-Seth GS Medical College & Member Secretary-KEM Hospital Ethics Committee
02.45 pm – 03.15 pm	Application Process for Accreditation	Dr Madhuri Jadhav Sr. Auditor-ADAMAS Clinical Quality Consulting & Chair-ISCR Training Council
03.15 pm – 03.45 pm	TEA BREAK	
03.45 pm – 05.15 pm	<p><u>Accreditation - Deciphering the Impact, Challenges and Action Items</u></p> <p>Panel Discussion:</p> <p>Moderator: Shehnaz Vakharia-Director, ADAMAS Clinical Quality Consulting, India</p> <ul style="list-style-type: none"> • Industry Perspective <ul style="list-style-type: none"> ○ Dr Partha Gokhale (Head-Clinical Operations, Boehringer-Ingelheim) ○ Dr Shekhar Dawkhar (Project Director-Clinical Trial Strategy & Design, Covance) • Ethics Committee Perspective <ul style="list-style-type: none"> ○ Dr Ravindra Ghooi (Chairperson-Ethics Committee, Jehangir Hospital Clinical Development Center and Sahyadri Hospitals, Pune; Director-Scientia Clinical Services) • Principal Investigator Perspective <ul style="list-style-type: none"> ○ Dr Vyankatesh Shivane (Consultant Diabetologist and Metabolic Physician, Dept. of Endocrinology, KEM Hospital) ○ Dr Siddharth Laskar (Consultant Radiation Oncologist & Member Secretary-IRB, Tata Memorial Hospital) 	
05.15 pm – 05.30 pm	Q & A and Wrap Up	

Registration details:

Delegate Fee: Rs. 2500/- per person

Last date of registration & Payment 27th May, 2015

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

Online registration (compulsory): - http://www.iscr.org/events_MemberRegistration.aspx

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, +91-9867318398
(Participation only for ISCR AMOs’ nominations and ISCR members)
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