



INDIAN SOCIETY FOR CLINICAL RESEARCH

13th Annual ISCR Conference

“Beyond New Regulations – Increasing participation and enhancing patient’s safety”

Organizing Committee: LOC – Kedar Nayak SOC – Seema Pai Pre-Conf – Murtuza Bughediwala

Pre-Conference workshop: CLINICAL RESEARCH: ENHANCING SITE AND INVESTIGATOR CAPABILITY BUILDING

Date: 23-Jan-2020, Thursday Timing: 09:00 am – 5:00 pm Venue: K J Somaiya Hospital & Research Center, Mumbai

Workshop Directors:

Dr. Seema Pai, Dr. Sneha Limaye, Mr. Nirmallya Das, Dr. Savita Rangarajan, Dr. Naveen Reddy

Description of the Workshop:

This workshop will be of benefit to investigators and clinical researchers involved in or interested to work in the field of Clinical Research and Trials to enhance their expertise in this domain.

Learning Objectives:

The objective of this workshop is to introduce the concept of 'research within practice' and explaining the newer advances in the 'clinical trial arena so as to enhance their capabilities and implement the same in routine medical practice.' This workshop will help practitioners as well as new entrants to provide basic knowledge on what is needed for setting up a clinical research unit, thus helping in capacity building for future Research Investigators.

Intended Audience:

- Investigators,
- To-be Investigators,
- Site Facing Community,
- Clinical Research Professionals.



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Agenda:

TIME	TOPIC	
9:00 - 9:30	Registration	
9:30 - 9:40	Introduction: <i>Welcome attendees, Purpose & Objectives of the workshop</i>	Mr. Nirmallya Das (Sr. Manager Clinops, Parexel International)
9:40 - 9:45	Welcome Address from host	Dr. Savita Rangarajan (Consultant Haematologist, K J Somaiya Hospital and Medical College, Mumbai)
9:45 - 10:00	Medical practice & research - are both possible?	Dr. Vyankatesh Shivane (Consultant Diabetologist & Metabolic Physician, KEM hospital, Mumbai)
10:00 - 10:30	Types of research, study designs and importance of a good research question	Dr. Priya Ranganathan (Prof of Anesthesiology, Tata Memorial Centre, Mumbai)
10:30 - 10:45	Tea Break	
10:45 - 11:30	Drug Development Process & Clinical Trial Phases Overview	Dr. Karan Thakkar (Site Relationship and Excellence Partner, Pfizer Limited)
11:30 - 13:00	Informed Consent Process A. AV Consenting – how do you do it well? (20mins) B. E-consent (20mins) C. Activity – Role Play (3 /4 grp) (20 Mins Preparation + 20mins Presentation + 10mins evaluation)	* AV Consenting – Dr. Nivedita Moulick (Consultant Internal Medicine, D Y Patil School of Medicine Nerul, Navi Mumbai, Mumbai) * E-consent – Ms. Renuka Neogi (Clinical Research Operations Manager, Sanofi)
13:00 - 14:00	Lunch Break	
14:00 - 14:30	* Panel Discussion - How do I find time for research - A busy clinician's perspective (20 mins) * Q & A (10 mins)	Moderator: Dr. Sneha Limaye (Investigator Council Member)



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TIME	TOPIC	
		Panelists: 1. Dr. Sewanti Limaye (Medical Oncologist, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai) 2. Dr. Mayur Mewada (Assistant professor, Department of Medicine, K J Somaiya Hospital and Medical College, Mumbai) 3. Dr. Manju Sengar (Consultant Hematologist, Tata Memorial Hospital, Mumbai) 4. Dr. Sujeet Rajan (Consultant Respiratory Physician, Bombay Hospital Institute of Medical Sciences, Mumbai)
14:30 - 15:30	Good Documentation Practice (ICH E6 R2): a. Overview & Best Practice Sharing (Lecture) b. Group Activity – Identify the errors and share observations (3/4 groups)	Mr. Kedar Nayak (Global Clinical Development Manager, GSK) A. 20 mins B. Preparation 20mins + Participant presentation 20mins
15:30 - 15:45	Tea Break	
15:45 - 16:45	An Ideal Clinical Research Set-up & benefits of a site network	Dr. Savita Rangarajan (Consultant Hematologist, K J Somaiya Hospital and Medical College) Ms. Jocelyn Walters (Research Delivery Manager, Somers Cancer Research Building, University Hospital)



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TIME	TOPIC	
		Southampton NHS Foundation Trust, UK)
16:45 - 17:00	Closing Discussion	Dr. Savita Rangarajan (Consultant Hematologist, K J Somaiya Hospital and Medical College) Dr. Sneha Limaye (Investigator Council - ISCR)

Registration and Payment details:

Registration fees:

Students (Group registration -5 or more)	Students	Academia	ISCR Member (For Individual & Corporate Members – AMOs)	Non-Member
1000 /-	2000/-	3000/-	Rs 4000	Rs 5000/-

Seat Limit - We have limited seats. Registration will close once the seat limit is reached.

All registered participants will get a “Certificate of Participation” from ISCR

Online registration - <http://www.iscr.org/events-registration/>

Online payment - <http://www.iscr.org/payment-events-workshops/>

Offline Payment - 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 Limited, The Capital 1802, 18th Floor, Plot No. C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

For any query, please feel free to write to info@iscr.org