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: Conference Room of K.J. Somaiya College of Physiotherapy, Somaiya Ayurvihar Complex, Eastern Express Highway, Everad Nagar, Sion, Mumbai 400 022

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.
# Agenda:

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<td>9:00 - 9:30</td>
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| 9:30 - 9:40 | Introduction: *Welcome attendees, Purpose & Objectives of the workshop*  
*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)  
*Dr. Nivedita Moulick (Consultant Internal Medicine, D Y Patil School of Medicine Nerul, Navi Mumbai, Mumbai)*  
B. E-consent (20mins)  
C. Activity – Role Play (3/4 grp) (20 Mins Preparation + 20mins Presentation + 10mins evaluation) *Moderated by Ms. Renuka Neogi* |
| 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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| 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 (Moderated by Mr. Kedar Nayak) |
| 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) |
**TIME** | **TOPIC**
---|---
16:45 - 17:00 | **Closing Discussion**

**Building, University Hospital Southampton NHS Foundation Trust, UK**

**Dr. Savita Rangarajan**  
(Consultant Hematologist, K J Somaiya Hospital and Medical College)  
**Dr. Sneha Limaye**  
(Investigator Council - ISCR)