Indian Society for Clinical Research (ISCR) in collaboration with Coimbatore Respiratory Society (CRS), Coimbatore presents One day Training Workshop on GCP and Local regulations for Clinical Trials on 14-October-2018 (Sunday) from 9:00 a.m. to 4:00 p.m.

Venue: Hotel Grand Regent, 708, Avinashi Road, Coimbatore – 641018.

EVENT HIGHLIGHTS

The objective of this training workshop is to discuss important Good Clinical Practice (GCP) topics with recent advances and updates on regulations for clinical trials in India, with focus on responsibilities of Investigators, clinical research site co-ordinators and ethics committee members.

TARGET AUDIENCE

Principal Investigators, Co-Investigators, Sub-Investigators, Clinical Research Coordinators, Hospital site staff, Ethics committee members, Chairpersons and Secretariat, Clinical research professionals from academia and industry, from Coimbatore and nearby cities.

REGISTRATION DETAILS

Open from **24st September 2018**

Registration fees:

Investigator/EC Member/Doctors/Academia – **Rs. 600/-**
Clinical Research/Site co-ordinator/staff – **Rs. 300/-**
Industry Clinical Research professionals – **Rs. 750/-**
Online Registration link – http://www.iscr.org/events-registration/
Online payment link – http://www.iscr.org/payment-events-workshops/
Offline payment: By Cheque in favour of "Indian Society for Clinical Research"

Limited to 40 participants ONLY

On spot registration as per availability

AGENDA ATTACHED

Organising and Scientific Committee:

Dr. Srikanth K. (Coimbatore)
Dr. Ramesh Jagannathan (Bengaluru)
Dr. Seema Pai (Mumbai)
Ms. Shobana (Coimbatore)

Training Workshop on GCP and Local regulations for Clinical Trials
Hotel Grand Regent, Avinashi Road, Coimbatore
14 October 2018

Time		Topic	
09:00	09:10 am	Welcome	Dr. Srikanth Krishnamurthy Consultant Pulmonologist, Sri Bala Medical Centre and Hospital, Coimbatore
09:10	09:20 am	Introduction & Agenda	Dr. Ramesh Jagannathan, Head-Clinical Development, Biocon Research Ltd., Bengaluru
09:20	09:50 am	Investigator and site staff responsibilities in Clinical Trials: Team work is the key	Dr. R. Balamurugan Consultant Diabetologist and Chief, Kovai Diabetes Speciality Centre and Hospital, Coimbatore
09.50	10.20 am	Subjects' Informed Consent in Clinical Trials: Focus on study participant(s) and requirements	Dr. Srikanth K.
10:20	10:50 am	Clinical Trial Protocol: Subjects(s) selection, follow-up, compliance and retention	Dr. Srikanth K.
10:50	11:10 am	Coffee/Tea Break	
11:10	11:50 am	Ethics in Clinical Research – Ethics Committee as a Pivot: Focus on recent requirements	Dr. Sudha Ramalingam, Registrar – Research, Professor- Community Medicine, PSG IMS & R, Coimbatore
11:50	12:20 pm	Sponsor's responsibilities: - Monitoring of Clinical Trials; Audits and Inspections	Dr. Seema Pai, Director & Head – India Cluster Global Site and Study Operations, Pfizer
12.20	12.40 pm	Safety reporting in clinical trials: Regulatory requirements and updates	Dr. Ramesh Jagannathan
12:40	01:10 pm	Panel Discussion - Regulations in India - Q&A	Dr. Srikanth K. Dr. R. Balamurugan Dr. Seema Pai Dr. Ramesh Jagannathan – Panel moderator
01:10	02:00 pm	Lunch break	
02:00	02:30 pm	ICH E6 (R2) – What are the changes to GCP?	Dr. Seema Pai
02:30	04:00 pm	Study Coordinator workshop : * Spot the errors and discuss * Group Exercise: Role Play	All faculty and participants
04:00	04:15 pm	Wrap up & Certificate Distribution	
04:15 pm		Coffee/Tea & End of Workshop	