



(Hindusthan Hospital)

Indian Society for Clinical Research (ISCR)

in collaboration with

Coimbatore Respiratory Society (CRS) & Hindusthan Hospital, Coimbatore

One-day workshop on Regulations, Good Clinical Practice and

Recent Developments in Clinical Trials

On Sunday, 10 November 2019

Venue: Hindusthan College of Arts and Science, Avinashi Road, Coimbatore

Highlights:

- **One-day workshop including topics on New drugs & Clinical trial rules 2019, Operational aspects of clinical trials, recent developments in drug development**
 - Participants will gain knowledge in **Good Clinical Practice (GCP) with a focus on recent regulations**
 - **Lectures, Panel discussion, Q & A and group discussions, facilitated by experienced Speakers**
- By the end of the workshop, participants should be able to get good understanding of Clinical Trials regulations in India, GCP, and responsibilities of different stakeholders in clinical research.
- **Faculty** from different Hospitals/Institutions of Coimbatore, Chennai, Industry Clinical Research professionals and ISCR members will be involved
 - **CME credits** for eligible participants (being applied with Tamil Nadu Medical Council)

Topics:

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| <ul style="list-style-type: none">• New CT Rules – Overview, highlights & Impact<ul style="list-style-type: none">○ Stakeholder's perspective• Ethics in Clinical Research<ul style="list-style-type: none">○ EC functioning and oversight – CTs and Academic clinical research• Responsibilities of Investigator, Site staff, Sponsor | <ul style="list-style-type: none">• ISCR overview & achievements• Development of Biosimilar Products<ul style="list-style-type: none">○ Clinical Trials requirements and Updates• Ongoing Safety evaluation of New Drug Products<ul style="list-style-type: none">○ Clinical Trials to Post-marketing• Case scenarios for Group discussions |
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Who should attend: Investigators, Ethics committee members, Doctors, Clinical Research Coordinators, Research staff/Study nurse involved in clinical studies, Pharmaceutical and CRO Industry personnel, Academic researchers, Medical, Pharmacy or Life-science post-graduate students

All participants to register via ISCR website (www.iscr.org) <https://www.iscr.org/events-registration/>

Last date of registration is 04 November 2019

Workshop registration Fees:

- 1. Investigator/Ethics committee member/Doctors/Academia – Rs. 1000 (For ISCR members – Rs. 800)**
- 2. Clinical Research site co-ordinator/research support staff/PG students – Rs. 500**
- 3. Industry Clinical Research professionals – Rs. 1200 (For ISCR members – Rs. 1000)**

For further details: Indian Society for Clinical Research (ISCR), ISCR Secretariat, Mumbai – 400 051

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Email: infor@iscr.org; secretariat@iscr.org ; Website: www.iscr.org

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Workshop on regulations, GCP and recent developments in Clinical Trials

Venue: Hindusthan College of Arts and Science, Coimbatore

Sunday, 10 November 2019

Time		Topic	Faculty/Speaker(s)
09:00	09:10 am	Welcome and Introduction, Agenda overview	Dr. Srikanth Krishnamurthy Sr. Consultant Pulmonologist, Hindusthan Hospital, Coimbatore
Operational Aspects of Clinical Trials			
09:10	09:50 am	Investigator responsibilities – GCP and Protocol compliance, Subject's Consent, enrolment and retention	Dr. Srikanth K.
09:50	10:20 am	Sponsor responsibilities – Study monitoring (Onsite, Centralised, Remote) and Quality	Ms. Salini James
10:20	10:40 am	Coffee/Tea	
New Drugs and Clinical Trials Rules 2019			
10:40	11:20 am	New CT Rules – Overview, Highlights and Impact	Dr. Gaurav Mathur, Director, Regulatory Affairs IQVIA
11:20	12:00 Noon	Ethics in Clinical Research: EC functioning and oversight – CTs and Academic clinical research	Dr. Poongothai S. Sr. Scientist and Head-Clinical Trials, Madras Diabetes Research Foundation, Chennai
12:00	12:45 pm	New CT Rules – Discussion from stakeholder's perspective Sponsor Investigator Academic Studies Ethics Regulatory BA/BE	Panel Discussion members: Dr Srikanth K Dr R. Balamurugan Dr Poongothai S. Dr Gaurav Mathur Ms. Salini James Dr Ramesh J. (Moderator)
12:45	01:45 pm	Lunch	



Time		Topic	Faculty/Speaker(s)
01:45	02:15 pm	ISCR–Overview and recent achievements	Dr. Gaurav Mathur
Workshop for Clinical Research Hospital/site staff and co-ordinators			
02:15	03:30 pm	(1) Role and responsibilities of site staff/research co-ordinator, key to success (2) Case scenarios - Spot the errors and discuss - Group Work/Exercise	Dr. Poongothai S. Mr. Karthik C., Mrs. Shobana B. All participants
03:30	03:50 pm	Coffee/Tea	
Recent developments in Drug Development and Clinical Research			
03:50	04:20 pm	Ongoing Safety evaluation of New Drug Products (Clinical Trials to Post-marketing)	Dr. Vijay Venkataraman MD and CEO, Oviya MedSafe, Coimbatore
04:20	04:50 pm	Development of Biosimilar Products: Clinical Trials requirements and Updates	Dr. Ramesh J.
04:50	05:00 pm	Summary, Certificate Distribution & End of Workshop	