



Indian Society for Clinical Research (ISCR)

in collaboration with

Hindusthan Hospital, Coimbatore



**Half-day workshop on Good Clinical Practice and
Regulatory Updates in Clinical Trials**

On Saturday, 20 November 2021

Venue: Hotel Landmark, Siddhapudur, Coimbatore.

Lunch : 12.30pm to 1.30pm

<i>Time</i>		<i>Topic</i>	<i>Faculty</i>
1:30pm	1:45pm	Welcome and Introduction, Agenda overview	Dr. Srikanth Krishnamurthy Sr. Consultant Pulmonologist, Head- Department of Clinical Research Hindusthan Hospital, Coimbatore
1:45pm	2:05pm	Key Highlights from New Drugs and CT Rules 2019	Dr. Ramesh Jagannathan Vice-President, Medical Affairs, Bharat Serum and Vaccines, Navi Mumbai
2:05pm	3:00pm	EC Overview - Member Specific Roles & Responsibilities, Informed Consent of study participants and other essential documents review; EC Initial & ongoing review	Dr. Usharani Pingali Professor & Head, Department of Clinical Pharmacology & Therapeutics Nizam's Institute of Medical Sciences, Hyderabad
3:00pm	3:30pm	EC Review of Clinical Trial Protocol, assessing risk versus benefit for Study Participants & Investigator Responsibilities	Dr. Srikanth Krishnamurthy Sr. Consultant Pulmonologist, Head-Department of Clinical Research Hindusthan Hospital, Coimbatore
3:30pm	3:50pm	Coffee/Tea	
3:50pm	4:20pm	SAE Reporting Requirements (CDSCO)- Investigator, Ethics committee and Sponsor responsibilities, SUGAM Portal overview	Ms. Suneetha Ganeshappa Manager – Regulatory affairs & Patient Safety AstraZeneca Pharma India Ltd., Bengaluru
4:20pm	4:50pm	SAEs and AEs in Clinical Trials – Causality assessment and Ongoing Product Risk versus Benefit assessment	Dr. Vijay Venkataraman MD and CEO, Oviya MedSafe, Coimbatore
4:50pm	5:15pm	Summary, Certificate Distribution & End of Workshop	