



## Indian Society for Clinical Research

### Regulatory Council Announces a One-Day workshop

### Favorable Regulatory Momentum for Future Clinical Research

#### Schedule:

Date	Time	Venue
09-Dec -17	8:30 am – 6:00 pm	Kolkata – Gahanananda Hall, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan

**INTRODUCTION:** This one-day workshop designed to present & clarify the evolving regulatory landscape especially over the last one year. Topics mentioned in this draft flyer will make this interface useful and interesting for professionals with Clinical Research.

**SCOPE:** To provide an overview of the recent developments governing the process of filing, review and approval of Clinical Trial applications, including relevant recent updates.

**TARGET AUDIENCE:** Regulatory & Clinical Research Associates of Sponsors & CROs, Pharmacy and Clinical Research students

## Agenda

Time	Topic	Speaker
8:30 to 9:00 am	Registration & Tea	
9:00 to 9:15 am	Welcome	Zonal Organizing Team
9:15 to 10:00 am	Raising Quality – Compliance Standards in Clinical Research	Zonal Organizing Team
10:00 to 10:45 am	Dialogue with EC members- empowerment, training, current practices – NABH Accreditation	Dr. Santanu Tripathi Dr. Sukanta Sen
10:45 to 11:15 am	<b>TEA BREAK</b>	
11.15 to 11.45 am	Clinical research in areas like medical devices, vaccines, Phase I trials and BA/BE studies	Dr. T. K. Pal Mr. Gaurav Mathur Dr. Saurendra Das
11.45 to 12.00 pm	Recent positive regulatory reforms	Regulator
12.00 to 1.00 pm	Break out session: real-life challenging cases	East zone organizing team
1.00 to 1.45 pm	<b>LUNCH BREAK</b>	
1:45 to 2:15 pm	Investigators experiences- challenging protocols, study conduct, expected support	Dr. T. K. Pal Dr. Prantar Chakraborty Dr. Chinmoy Bose TBC
2:15 to 3.00 pm	e-governance and digitalization impact! SUGAM initiative by CDSCO Sharing Experiences – Industry and Regulators	Mr. Gaurav Mathur Regulators
3.00 – 3:30 pm	<b>TEA BREAK</b>	

<p>3:30 to 5:30 pm</p>	<p><b>Panel Discussion:</b>          Forward momentum for clinical research</p> <p>Panelists from-</p> <ul style="list-style-type: none"> <li>• Industry experts</li> <li>• Regulators</li> <li>• EC representatives</li> <li>• Investigator</li> <li>• SEC experts</li> </ul>	<p>Regulator          Dr. Santanu Tripathi          Dr. Prantar Chakroborty          Dr. Chinmoy Bose</p>
<p>5.30 – 5:45 pm</p>	<p>Wrap Up and Conclusions</p>	<p>Zonal organizing team</p>