



INDIAN SOCIETY FOR CLINICAL RESEARCH

Regulatory Council- North Chapter

in collaboration with

Jamia Hamdard University

presents

One-Day Workshop on

**“New Regulations to Further Strengthen
Clinical Research in India”**

08-Nov-2019

At

**Jamia Hamdard University
New Delhi**

Registration Link @ <https://www.iscr.org/events-registration/>

Fee Details: Registration fees – Academia – Rs. 1000/-

For Payment : [Click here](#)

Registration fees – Ethics Committee members and CRCs – Rs. 2000/-

For Payment : [Click here](#)

Registration fees – ISCR Members – Rs. 3500/-

For Payment : [Click here](#)

Registration fees – Non Members – Rs. 4500/-

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Agenda		
Time	Topic	Speaker
08.30 to 09.15	Registration & Tea	
09:15 to 09:30	Welcome – Introduction to ISCR	ISCR RC/NC representative
09:30 to 11:30	New Drugs and Clinical Trials Rules, 2019	
09:30 to 10:00	New CT Rules – Overview, Highlights and Impact	Invited Speaker: Mr. Dhananjay Sable (CDSCO)
10:00 to 11:15	<i>New CT Rules – Discussion from stakeholder’s perspective</i> <i>Sponsor</i> <i>Investigator</i> <i>Academic Trials</i> <i>Ethics Members</i> <i>Regulator</i> <i>BA/BE</i>	Invited members: Dr. Y.K Gupta (Panel Chair) Rohit Arora (Eli Lilly) Dr. Sameer Bakshi (AIIMS) Dr. Divya (Jamia Hamdard) Dr. Prem Kapoor (Jamia Hamdard) Mr. Dhananjay Sable (CDSCO) Dr. Sandeep Sharma (Jubilant)
11:15 to 11:30	Q&A Session	
11:30 to 11:45	TEA BREAK	
11:45 to 13:00	Operational Aspects of Clinical Trials	
11:45 to 12.15	SAE Reporting Submission Overview	Invited Speaker: Dr. Mita Nandy (Sadiq Nagar CDSCO)
12.15 to 12:45	SUGAM submissions – Tips and Tricks	Invited Speaker: Ms. Sneha Gupta & Sana Noorie (Sanofi, India)
12:45 to 13:00	Q&A Session	
13:00 to 14:00	LUNCH BREAK	
14:00 to 15:30	Advances in Clinical Research	
14:00 to 14:45	Current Regulatory Scenario for conducting BA/BE studies in India	Invited Speaker: Dr. Sandeep Sharma (Jubilant)
14:45 to 15:30	Panel Discussion on Medical Device The way forward for Clinical Investigation and risk assessment in Medical Devices	Invited members: Mr. Rahul Chauhan- (RB) Ms. Latika Vats (Medtronic) Ms. Sahjogita Kathuria (Terumo) Ms. Gunjan Verma (Asia Actual)
15:30 to 15:45	TEA BREAK	
15:45 to 17:00	Break Out Session Group Activity and Presentations	
17:00 to 17:30	Wrap-up and Thank you	ISCR RC-SC Organizing Team