



Nizam's Institute of Medical Sciences

INDIAN SOCIETY FOR CLINICAL RESEARCH

Regulatory Council- South Chapter

in collaboration with

Basavatarakam Indo American Cancer Institute and Research Centre, Hyderabad

Apollo Research and Innovations, Apollo Hospitals, Hyderabad

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Nizams Institute of Medical Sciences, Hyderabad

presents

One-Day Workshop on
“New Regulations to Further Strengthen
Clinical Research in India”

20th December 2019 (Friday)

at

The auditorium, 4th floor, Jamsetji Tata Memorial Block (Block II)

Basavatarakam Indo American Cancer Institute and Research Centre

Hyderabad

Agenda

Time	Topic	Speaker
08:30 to 09:00	Registration & Tea	
09:00 to 09:15	Welcome & Introduction to ISCR	<i>ISCR Regulatory Council/South Chapter Representative – Dr. Gaurav Mathur</i>
09:15 to 12:30	SESSION I - New Drugs and Clinical Trials Rules, 2019	
09:15 to 10:00	New CT Rules – Overview, Highlights and Impact	<i>Dr. Gaurav Mathur – Director, Regulatory Affairs (IQVIA)</i>
10:00 to 10:15	TEA BREAK	
10:15: to 12:30	New CT Rules – Discussion from stakeholder’s perspective: <ul style="list-style-type: none"> • <i>Sponsor-CRO</i> • <i>Investigator</i> • <i>Ethics Committee</i> • <i>BA/BE studies</i> • <i>IT solutions</i> • <i>SMO</i> 	<p><i>Sponsor-CRO: Dr. Agam Shah, Lead Clinical Operations, Dr.Reddys Laboratories Limited.</i></p> <p><i>Investigator: Dr. Krishna Mohan, Consultant -Medical Oncology Basavatrakam Indo American Cancer Institute and Research centre</i></p> <p><i>Ethics Committee: Dr. Sreedhar, Member Secretary, S2J Ethics Committee, Head-Clinical Research Care</i></p> <p><i>BA/BE Studies: Dr. Rajendra Prasad, CEO, - Jeevan Scientific</i></p> <p><i>IT solutions: Mr Mujeebuddin Founder and CEO: Clinosol Research Private Limited</i></p> <p><i>SMO: Dr Y Dinesh, Group Head, GCRS, Gleneagles Global Hospitals Group</i></p>
12:30 to 13:00	Q&A Session	
13:00 to 14:00	LUNCH BREAK	
14:00 to 15:30	SESSION II - Operational Aspects of Clinical Trials	
14:00 to 14:30	Legal considerations of conducting clinical trials in India	<i>Ms. Smitha Chandrashekaraiah – Director, Legal (IQVIA)</i>

14:30 to 15:00	SUGAM submissions – Tips and Tricks	<i>Ms Sindhuja, Regulatory affairs specialist, Dr.Reddys Laboratories Limited.</i>
15:00 to 15:30	Vaccine Clinical Trial	<i>Dr Rajeshri Manikyam Senior Manager, Medical Affairs Bharat Biotech International Limited</i>
15:30 to 15:45	TEA BREAK	
15:45 to 17:15	SESSION III - Panel Discussion	
15:45 to 17:15	<p>Topic:</p> <p>“CHALLENGES IN GOVERNANCE AND REGULATORY COMPLIANCE WHILE CONDUCTING CLINICAL TRIALS”</p> <p>Q&A Session</p>	<p>Panelists:</p> <p>Representatives from:</p> <ul style="list-style-type: none"> • Regulator- TBD • Academia: Dr Usha Rani (Prof and Head, Pharmacology, NIMS, Hyd) • Investigator: Dr Beerappa Nagari Professor of Surgical Gastroenterology (NIMS) • Ethics Committee: Dr Suseela, Senior Consultant Pathologist , Member secretary Institutional Ethics committee Kodandapani Basavatrakam Indo American Cancer Insitute and Research centre • BA/BE - Dr. Mukesh Agrawal - Vice President , Vimta Labs • SMO –Mr Praveen, Site manager, ARI(Apollo Research and Innovations) <p>Moderator: Ms. Chandana Pal , Accreditations and Quality Systems Incharge , ARI(Apollo Research and Innovations)</p>
17:15 to 17:30	Wrap-up and Thank you	ISCR RC-SC Local Organizing Team

Registration and Payment details:

Registration fees:

Clinical Research Coordinators	Academia	Ethics Committee members	ISCR Member (For Individual & Corporate Members – AMOs)	Non-Member
Rs 750/-	Rs 1000/-	1500/-	Rs 3500/-	Rs 4500/-

Seat Limit - We have limited seats. Registration will close once the seat limit is reached.

All registered participants will get a “Certificate of Participation” from ISCR

Online registration - <http://www.iscr.org/events-registration/>

Online payment - <http://www.iscr.org/payment-events-workshops/>

Offline Payment - Cheque/DD payable at Mumbai should be made in favor of “Indian Society for Clinical Research” & mailed to us at ISCR Secretariat, c/o Pfizer Limited, The Capital 1802, 18th Floor, Plot No. C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

For any query, please feel free to write to info@iscr.org