



Clinical Trial Protocol Development - A Workshop for Clinical Research Professionals

29th and 30th March 2017, Holiday Inn, Aero City, New Delhi, INDIA

The Indian Society for Clinical Research (ISCR) presents a two- day Clinical Research Workshop on *Clinical Trial Protocol Development* at Holiday Inn, Aero City, New Delhi on 29th and 30th March 2017.

Highlights:

This two-day workshop aims at introducing workshop participants to several aspects of clinical trial protocol development including study objectives, expected outcomes from each stage of clinical cycle, relevant regulations, study design and methodology. On the first day, the speakers from Industry and Academia will focus on scientific and ethical considerations, and also try to bring about similarities and differences in developing and writing clinical study protocols and Investigators and Pharma perspectives. The sessions on specific topics on the second day will help participants better understand the basic statistical concepts necessary for study development. A panel discussion on competencies required in Regulatory Medical Writing will further help our young professionals become successful clinical research professionals.

Who should Attend:

Physicians, Surgeons & Medical Residents involved in Patient Research; Biostatisticians; Medical Writers; Medical, Pharmacy, Statistics or Life-science students or professionals interested in Clinical Research; Research Scholars/Scientists interested in Clinical Research; Clinical Investigators and Health Care Professionals from Pharmaceutical Industry, Contract Research Organizations, Government Agencies, Non-profit Organization/Associations, and Academia.

Workshop Speakers:

Janssen, Novartis, GSK, Novo Nordisk, Karmic Life Sciences, TCS, Kinapse, Jaypee Hospital, PFC Pharma Focus, PMSS TuracoZ and APCER

Scientific Committee		Local Organizing Committee
Medical Writing	Biostatistics	
Dr. Rajesh Kher (Janssen)	Dr. Prashant Kirkire (Karmic)	Hitesh Manchanda (Kinapse)
Vaibhav Jain (GSK)	Tushar Sakpal (TCS)	Pinky Sharma (TuracoZ)
Dr. Pooja Phogat (Kinapse)		Ajay Pradhan (Janssen)
Annie Jose (Novo Nordisk)		Venkat Pola (Tech Observer)

Agenda Day 1: Wednesday, 29 th March 2017		
Time	Session	Speakers
08:30 - 09:30	Registration and Tea/Coffee	
Session 1 - Clinical Research		
09:30 - 10:00	Inauguration and Introduction to the Workshop	Dr. Rajesh Kher, Janssen; Annie Jose, Novo Nordisk
10:00 - 10:45	Clinical Development - From Lab to Market	Dr. Hariprasad Madhamshetty, Novartis
10:45 - 11:00	Tea/Coffee	
Session 2 - Regulatory Requirements		
11:00 - 11:30	Clinical Trial Protocol - Regulatory Requirements	Ankita Arora, Kinapse
11:30 - 12:15	Registering a Clinical Trial	Dr. Pooja Phogat, Kinapse
12:15 - 13:00	Panel Discussion: Competencies Required to be a Successful Medical Writer	Dr. Natasha Das, PFC Pharma (Moderator); Annie Jose, NovoNordisk; Dr. Namrata Singh, Turacoz; Dr. Sanjukta Bhattacharyya, APCER; Ms. Choo Hui Hwa, Tech Observer
13:00 - 14:00	Lunch	
Session 3 - Study Design and Protocol Development		
14:00 - 14:45	Clinical Study Design - Conventional and New Approaches	Dr. Prashant Kirkire, Karmic
14:45 - 15:30	Developing & Authoring a Clinical Trial Protocol – A Medical Writers Perspective	Dr. Payal Bhardwaj, TCS
15:30 - 15:50	Tea/Coffee	
Session 4 - Developing Effective Protocols		
15:50 - 16:25	Clinical Trial Protocol - A Clinical Investigator's Perspective	Dr. Esha Kaul, Jaypee Hospital
16:25 - 17:00	Protocol Amendments - Types, Impact, and Management	Vaibhav Jain, GSK
17:00 - 17:45	Panel Discussion: Alternate Careers for Established Medical Writers	Dr. Shoibal Mukherjee (Moderator); Dr. Rajesh Kher & Dr. Lakhwinder Batolar, Janssen; Shabbir Rangawala, Independent Consultant; Dr. Seema Gurbani, TCS
17:45 - 18:00	Concluding Remarks & Certificate Distribution	Vaibhav Jain, GSK

Agenda Day 2: Thursday, 30 th March 2017		
Time	Session	Speakers
08:30 - 09:30	Registration and Tea/Coffee	
09:30 - 10:00	Introduction to the Workshop	Tushar Sakpal, TCS
Session 1 - Basics Concepts of Statistics		
10:00 - 11:30	Statistics for Non-statisticians	Dr. Prashant Kirkire, Karmic
11:30 - 12:00	Tea Break	
Session 2 - Basics of Data Analysis and Presentation		
12:00 - 13:30	Unrevealing a Statisticians Mind - How to Visualize and Summarize Data	Krishnendu Biswas, Cognizant
13:30 - 14:30	Lunch Break	
Session 3 - Concepts of Survival Analysis		
14:30 - 16:00	Survival Analysis - Data, Analysis and Interpretation and Related Challenges	Tushar Sakpal, TCS
16:00 - 16:30	Tea Break	
16:30 - 17:30	Group Discussion - Challenges in Managing Survival Related End Points	Tushar Sakpal, TCS (Moderator); Dr. Prashant Kirkire, Karmic; Dr. Seema Gurbani, TCS; Dr. Ajay Kher, Fortis Escorts
17:30 - 17:45	Concluding Remarks and Certificate Distribution	Dr. Prashant Kirkire, Karmic Dr. Rajesh Kher, Janssen



Registration Details

	Category	Registrations on or before 21 st March 2017		Spot Registrations on 29 th and 30 th March 2017	
		Single Day	Both Days	Single Day	Both Days
Delegate Fees	Academia	Rs. 1250/-	Rs. 2000/-	Rs. 1500/-	Rs. 2500/-
	ISCR Member	Rs. 2000/-	Rs. 3000/-	Rs. 2500/-	Rs. 3500/-
	Non Member	Rs. 2500/-	Rs. 3500/-	Rs. 3000/-	Rs. 4000/-
For group early registrations on or before 21 st March 2017, 1 is free with 5 registrations (pay for 4, additional 1 is free)					
For group spot registrations on 29 th and 30 th March 2017, 1 is free with 5 registrations (pay for 4, additional 1 is free)					

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” & mail to us at:
ISCR Secretariat, c/o Pfizer Centre, The Capital 1802, 18th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (E), Mumbai - 400051

For any query please contact on Email: info@iscr.org Telephone: +91-8454827775

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Complimentary Table /Booth Space at Venue	Yes/ (Medium)	Yes/ (Medium)	Yes (Small)	Yes/ (Medium)
Free Delegate Registration	Four	Three	Two	Four
Logo on Flyer	Yes	Yes	Yes	Yes
Logo on Standees /Banner	Yes	Yes	Yes	Yes
Logo on Delegate Kit	No	No	No	Yes

*ISCR is the sole sponsor of this event.