



Indian Society for Clinical Research Presents
Medical Writing: Beyond Protocols, Investigator's Brochures and Study Reports
Club Botanika, Jayabheri Enclave, Gachibowli, Hyderabad, Telangana, India
Date: 05-06 December 2019

Highlights: This workshop is intended to introduce the participants to documents other than the regular clinical trial documents like protocols, investigator's brochures and study reports that are written by medical writers during the life-cycle of a drug in development. This workshop is for new writers and experienced writers who are new to performing systematic literature reviews and writing various documents like informed consent documents, plain language summaries, clinical overviews, drug label updates and reports for medical devices. Our experienced workshop faculty will provide the participants with interactive exercises and hands-on trainings on writing of these documents, besides providing an overview of the role of medical writers as project managers in supporting multifunctional clinical teams in development of these documents.

By the end of this two-day workshop, each participant should be able to understand the basic structuring and drafting of these documents and have a fair understanding of language, presentation, key messaging and regulations that govern these documents.

Who Should Attend: Medical Writers, Publication Writers, Research Scholars, Scientists, and Health Care Professionals from Pharmaceutical Industry, Contract Research Organizations, Government Agencies, Non-profit Organizations/Associations, and Academia, Medical, Pharmacy or Life-science Students or Professionals interested in making a career in medical writing

Convener: Rajesh Kher (Janssen)

Chairperson: Anushila Vaishali (IQVIA)

Scientific Committee:

Roopa Basrur (Parexel)

Sunita Cheruku (Consultant)

Hari Prasad Madhamshetty (Novartis)

Local Organizing Committee:

Arvind Semwal (Parexel)

Harika Bollampally (IQVIA)

Bhavan Kumar Vengala (HCL)

DATE	TIME	TOPIC	WORKSHOP LEADERS
05-Dec-2019, Thursday DAY 1	8.30 – 9.00	Registration	
	9.00 – 9.30	Introduction/ Welcome	Anushila Vaishali (IQVIA)
	9.30 – 11.00	Writing Informed Consent Documents; Interactive Writing Exercise	Viji Ramesh (Parexel)
	Tea Break (11.00 – 11.30)		
	11.30 – 13.00	Writing Plain Language Summaries; Interactive Writing Exercise	Vidhi Vashisht (Kinapse – a Syneos Company)
	Lunch Break (13.00 – 14.00)		
	14.00 – 15.30	How to Perform and Interpret A Systematic Literature Review; Interactive Exercise	Mahendra Rai (IQVIA)
	Tea Break (15.30 – 16.00)		
16.00 – 17.00	Panel Discussion – Lateral Movement Options for Medical Writers for Long Term Career Growth	Roopa Basrur (Parexel) - Moderator	
END OF DAY 1			
06-Dec-2019, Friday DAY 2	9.00 – 9.05	Introduction to the Day	
	9.05 – 9.30	Regulatory Requirements for Medical Devices with Focus on Clinical Investigation and Clinical Evaluation	Abhijit Khompi (GSK)
	9.30 – 11.00	Writing Clinical Evaluation Reports; Interactive Writing Exercise	Sridhar Bunga (HCL)
	Tea Break (11.00 – 11.30)		
	11.30 – 13.00	Clinical Overviews – Types, Content, Language, and Relevance in Drug Labelling; Interactive Writing Exercise	Amit Goombar, Novartis
	Lunch Break (13.00 – 14.00)		
	14.00 – 15.30	The Science and Process Behind Global Labeling as Strategy Tool; Interactive Exercise	PV Sriram Narayanan (Novartis), Amrish Huddar (Novartis)
	Tea Break (15.30 – 16.00)		
16.00 – 17.00	Panel Discussion: Building Successful Sponsor-Service Provider Relationship	Sunita Cheruku - Moderator	
17.00 – 17.30	Certificate Distribution and Vote of Thanks		
END OF DAY 2			

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

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

*ISCR is the sole sponsor of this event

Registration Details (Fees in INR):

Delegate Fees#		By 31 Oct 2019	Between 01 Nov 2019 – 30 Nov 2019	Registrations after 30 Nov 2019
	Student	Rs. 2500/-	Rs. 3000/-	Rs. 3500/-
	ISCR Member	Rs. 3500/-	Rs. 4500/-	Rs. 5500/-
	Non ISCR Member	Rs. 5000/-	Rs. 5500/-	Rs. 6500/-

Group registration discount: 1 registration free in a block of 5 registrations

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 contact ISCR on [Email: info@iscr.org](mailto:info@iscr.org) Telephone: +91-8454827775

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Free Delegate Registration	Five	Three	One	Three
Logo on Flyer	Yes	Yes	Yes	Yes
Logo on Standees/Banner	Yes	Yes	Yes	Yes
Logo on Delegate Kit	No	No	No	Yes
Promotional Material on Delegate Tables	Yes	Yes	Yes	Yes



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