



Indian Society for Clinical Research

Presents

A Workshop on “Key Safety Documents in Regulatory Writing”

Radisson Blu Atria, Palace Road, Bengaluru, Karnataka, India

15th and 16th November 2019

Highlights: Safety is a widely discussed topic across all the functions within clinical research and health care industry. There are several documents in Regulatory Medical Writing focused on reporting on study level safety and patient level safety. Considering the importance of this subject, ISCR brings you a two-day program on “Key Safety Documents in Regulatory Writing”. All individual mini-workshops will be conducted by industry experts with rich experience in writing safety documents. The two day’s program will have two tracks to cover some important topics on reporting on patient safety. Participants have a choice to attend either of the two tracks. The mini-workshops will cover introductory, intermediate, and advance level topics which include Preparation of CSR Patient Narratives, Development Safety Update Reports, and Risk Management/Mitigation Plans. Participants will be given group exercises on each topic followed by discussions on their outputs which will be moderated by the workshop leaders.

Who Should Attend: Medical Writers working with Pharmaceutical Industry or Contract Research Organizations, Biostatisticians, Clinical Scientists, Clinical Data Managers, Investigators, Research Scholars or Scientists interested in Clinical Research, HealthCare Professionals from Government Agencies, Non-profit Organizations/Associations and Academia, and Medical, Pharmacy, Statistics or Life-science Students or Professionals interested in Clinical Research.

Convener: Dr.Rajesh Kher (Janssen R&D)		
Chairperson: Dr.Shivanand Jigajinni (IQVIA)		
Scientific Committee		Local Organizing Committee
Bijesh Manikoth (Indegene)	Dr.Pavan Yenduri (Syneos Health)	M Sudheer Kumar (Eli Lilly)
Dr.Deepa Trivedi (TCS)	Dr.Rajesh Kher (Janssen R&D)	Utkarsh Alok (IQVIA)
Dr.Intesar Khatri	Dr.Rupesh Thorat (SiroClinpharm)	
Keerthika Gogula	Shreya Bhargava (Parexel)	
Dr.Lakshmi Priya Muthu (Accenture)	Dr.Sushma Narayan (Covance)	

Dr.Nirmal Kumar Shankar (AstraZeneca)	Dr.Thejaswi NC (MMS Holdings)	
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Key Safety Documents in Regulatory Writing - Workshop by ISCR
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Track 1-Day 1

Date	Time	Topic	Speaker
Friday, 15th November	08:30-09:30	Registration/ Introduction/ Welcome	
	09:30-10:30	Introduction to Developmental Safety Update Report (DSUR)	Dr.Pavan Yenduri
	Tea Break (10:30-11:00)		
	11:00-12:30	Writing DSURs	Dr.Nirmal Kumar
	12:30-13:00	Preparation of DSURs – Best Practices & Project Management	Dr.Rupesh Thorat
	Lunch Break (13:00-14:00)		
	14:00-15:00	Exercise on Writing a DSUR	Dr.Nirmal Kumar and Dr.Rupesh Thorat
	15:00-16:00	QC and Content Review of DSURs	Dr.Rupesh Thorat
	Tea Break (16:00-16:30)		
16:30-17:30	Exercise on Data QC and Content Review	Dr.Nirmal Kumar and Dr.Rupesh Thorat	

Closing Remarks and End of Day 1

Track 1-Day 2

Saturday, 16th November	09:00-10:00	Panel Discussion – Regulatory Perspectives in Analyzing Benefit and Risk - Common for Both Tracks	
	Tea Break (10:00-10:30)		
	10:30-11:30	Introduction to Risk Management Plan (RMP)	Keerthika Gogula
	11:30-13:00	Writing RMPs	Dr.Intesar Khatri
	Lunch Break (13:00-14:00)		
	14:00-15:30	Exercise on Writing RMP including QC	Dr.Nirmal and Keerthika
	Tea Break (15:30-16:00)		
16:00-17:00	Harmonization of Data Across Safety Deliverables	Dr.Rupesh Thorat	

End of Workshop/Vote of Thanks

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Track 2-Day 1

Date	Time	Topic	Speaker
Friday, 15th November	08:30-09:30	Registration/ Introduction/ Welcome	
	09:30-10:30	Introduction to Patient Narratives	Shreya Bhargava
	Tea Break (10:30-11:00)		
	11:00-11:30	MedDRA – Importance of Understanding MedDRA	Dr.Lakshmi Priya
	11:30-12:15	Introduction to Source Documents for Writing Patient Narratives	Dr.Thejaswi NC
	12:15-13:00	Writing A Good Patient Narrative	Shreya Bhargava
	Lunch Break (13:00-14:00)		
	14:00-14:45	Best Practices in Content and Data Quality Review of Patient Narratives	Dr.Lakshmi Priya
	14:45-15:15	Narrative Writer: Project Management and Other Skillsets	Dr.Deepa Trivedi
	15:15-16:00	Exercise on Writing Patient Narratives	Shreya Bhargava and Bijesh Manikoth
Tea Break (16:00-16:30)			
16:30-17:30	Cardiology and Neurology Narratives	Bijesh Manikoth	

Closing Remarks and End of Day 1

Track 2-Day 2

Saturday, 16th November	09:00-10:00	Panel Discussion – Regulatory Perspectives in Analyzing Benefit and Risk - Common for Both Tracks	
	Tea Break (10:00-10:30)		
	10:30-11:30	Diabetes Narratives and Adjudication Events	Dr.Pavan Yenduri
	11:30-13:00	Oncology Narratives	Dr.Sushma Narayan
	Lunch Break (13:00-14:00)		
	14:00-15:00	Narratives for Medical Devices	Bijesh Manikoth
	14:45-15:30	The Narrative Chat-Room: Talk and Learn Session	Bijesh Manikoth & Shreya Bhargava
	Tea Break (15:30-16:00)		
16:00-17:00	Automation in Clinical and Safety Narratives: Current Situation and Way Forward	Dr.Rajesh Kher & Dr.Deepa Trivedi	

End of Workshop/Vote of Thanks

ISCR SPONSORSHIP CATEGORIES*

Sponsorship Offerings	Platinum Sponsor Rs. 50,000	Gold Sponsor Rs. 30,000	Silver Sponsor Rs. 15,000	Sponsor for Kit-Bag Rs. 50,000
Complimentary Table /Booth Space at Venue **	Yes (Medium)	Yes (Medium)	No	Yes (Medium)
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

*ISCR is the sole sponsor of this event; **Two additional free registrations in lieu of table/booth space

Delegate Fees [#]		Early Bird until 30 Sep 2019	Between 01 Oct to 15 Oct 2019	On or after 16 Oct 2019
	ISCR Member		Rs. 3500/-	Rs. 4500/-
Non ISCR Member		Rs. 4500/-	Rs. 5500/-	Rs. 7000/-

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

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

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