



A Workshop on Clinical Study Report Development and A Satellite Symposium on Medical Writing as a Career Choice

Nizam's Institute of Medical Sciences, Hyderabad, Telangana, India (02-03 August 2018)

Agenda

Day 1: 02-August-2018		
Time	Topic	Speaker
8:30 AM – 9:30 AM	Registration	Organizing Committee
9:30 AM – 9:40 AM	Welcome speech	Dr. Usha Rani Pingali (NIMS)
9:40 AM – 9:50 AM	ISCR orientation	Vaibhav Jain (GSK)
9:50 AM – 10:00 AM	Introduction to the programme	Dr. Sailaja Devi (Novartis)
10:00 AM – 10:45 AM	Clinical Study Report- the regulatory framework and beyond <ul style="list-style-type: none"> - The regulatory framework - Purpose and audience of a CSR - How to write “fit for purpose” CSR <i>Format: Presentation</i>	Shakti Rath (Novartis)
10:45 AM – 11:15 AM	Tea	
11:15 AM – 12:45 PM	Writing succinct introduction and methods sections <ul style="list-style-type: none"> - How to transcribe from protocol - How to integrate amendments - Writing statistical methodology in CSR <i>Format: Presentation, exercise & discussion</i>	Dr. Sailaja Devi (Novartis)& Dr. Reema Bardhan Acharya (Eli Lilly)
12:45 PM – 1:30 PM	Lunch	
1:30 PM – 2:00 PM	Interactive activity	Pinky Sharma (Virtue Insight)
2:00 PM – 2:40 PM	Leading a data review and key messaging meeting before embarking on writing the results <i>Format: An interactive role play</i>	Dr. Reema Bardhan Acharya(Eli Lilly) - Moderator
2:40 PM to 3:00 PM	Tea	
3:00 PM to 4:00 PM	Study population results – A reflection on planned study population <i>Format: Presentation, exercise & discussion</i>	Naimanulla Khan (Parexel)
4:00 PM to 5:00 PM	How do I plan my CSR? Tips & tricks of project management <i>Format: Panel discussion</i>	Dr. Rajesh Kher (Janssen) - Moderator
5:00 PM to 5:15 PM	Wrap Up Day 1	Dr. Sailaja Devi (Novartis)

Day 2: 03-August-2018		
Time	Topic	Speaker
8:30 AM – 10:00 AM	Interpretation of efficacy results (Statistically significant and non-significant results, sensitivity analysis etc.) <i>Format: Presentation, exercise & discussion</i>	Amit Goomber (Novartis)& Dr. Kavitha Muchandi(Parexel)
10:00 AM – 11:20 AM	Interpretation of safety results and narrative planning (Clinically significant and non-significant results, shift tables etc.) <i>Format: Presentation, exercise & discussion</i>	Annie Jose (Novo Nordisk)
11:20 AM – 11:35AM	Tea	
11:35AM – 12:15PM	Authoring discussion and conclusion sections <i>Format: Presentation & discussion</i>	Annie Jose (Novo Nordisk)& Amit Goomber (Novartis)
12:15 PM –1:15 PM	Systematic approach to perform QC review of a CSR <i>Format: Presentation, exercise & discussion</i>	Dr. Archana Pasi (TCS)
1:15 PM -2:00 PM	Lunch and Networking	
Symposium		
2:00 PM – 2:45 PM	Introduction to drug discovery and clinical development	Dr. Rajesh Kher (Janssen)
2:45 PM – 3:30 PM	Medical writing as a career - Competencies required to start a career in medical writing	Dr. Sunita Reddy Cheruku (Novartis)
3:30 PM – 4:00 PM	Tea	
4.00 PM – 4:30 PM	Meet the experts - Open forum	Dr. Rajesh Kher (Janssen) - Moderator
4:30 PM – 5:30 PM	Wrap Up and Certificate Distribution	Organizing Committee

Conveners:

Dr. Usharani Pingali (NIMS)
Dr. Rajesh Kher (Janssen)

Scientific Committee:

Dr. Sailaja Devi (Novartis) - Chairperson
Vaibhav Jain (GSK)

Local Organizing Committee:

Vaibhav Jain (GSK)
Dr. Shovan Padhy (NIMS)
Dr. G. Srinivas (NIMS)
Pinky Sharma (Virtue Insight)