



Indian Society for Clinical Research Presents

A Workshop on Adopting CORE Reference - Clarity and Openness in Reporting: E3 Based in Writing Disclosure-friendly Clinical Study Reports

Stellar Business Park, Sector-62, Noida, India
11 November 2019

Highlights: Interventional clinical trials conducted in the regulated clinical environment are reported using ICH E3 Guideline: Structure and Content of Clinical Study Reports (CSRs; 1995) and ICH E3 Guideline: Structure and Content of Clinical Study Reports Questions & Answers (R1; 2012). Regulators around the world are increasingly asking for transparent disclosure of clinical trial data to the public, and there is an increased awareness of the importance of anonymized clinical study results disclosure. For these disclosures, CSR remains a vital source document.

It is highly pertinent to understand how ICH guidelines are applied in CSR preparation to disclose results as accurately as possible, along with what can be minimized to prepare a disclosure ready CSR. CORE Reference is a user manual to help medical writers navigate relevant guidelines while authoring a public-disclosure ready CSR with a harmonized structure across Pharma companies.

This workshop is for medical writers who would like to upgrade their skills to be able to write CSRs in accordance with the principles of data transparency in clinical trials. Our experienced workshop faculty will provide the participants with interactive exercises and hands-on trainings on writing a disclosure-ready CSR. By the end of this one-day workshop, each participant should be able to understand the utility of incorporating principles and suggestions of CORE Reference in structuring and drafting of a content-driven disclosure-ready CSR.

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

Convener: Rajesh Kher, Janssen

Chairperson: Shalini Dwivedi, Kinapse – a Syneos Health Company

Scientific Committee

Reema Bardhan, Eli Lilly
Payal Bharadwaj, TCS
Hetal Shah, MeWriT

Local Organizing Committee

Ajay Pradhan (Janssen)
Hitesh Manchanda, Kinapse – a Syneos Health Company

Agenda:

TIME	TOPIC	SPEAKERS
8:30 to 9:00	Registration	
9:00 to 9:30	Welcome & Introduction	Shalini Dwivedi (Kinapse)
9:30 to 11:00	Introduction to the CORE Reference: How it relates to the Trial Transparency Initiatives + Exercises	Shalini Dwivedi (Kinapse)
TEA BREAK [11:00 – 11:15]		
11:15 to 12:45	CORE Reference: Practical Implementation in Writing CSRs + Exercises	Hetal Shah (MeWriT)
LUNCH & NETWORKING [12:45 – 13:45]		
13:45 to 15:15	Lean Writing & Balancing Scientific Accuracy in CSRs + Exercises	Reema Bardhan (Eli Lilly)
TEA BREAK [15:15 – 15:30]		
15:30 to 17:00	Importance of Structured Authoring of Regulatory Documents + Exercises	Payal Bhardwaj (TCS)
17:00 to 17:30	Open Forum, Certificate Distribution and Vote of Thanks	All Speakers

Registration Details (Fees in INR):

Delegate Fees#		By 30 Oct 2019	Registrations after 30 Oct 2019
	ISCR Member		Rs. 2500/-
Non ISCR Member		Rs. 3500/-	Rs. 5500/-
# Group registration discount: 1 registration free in a block of 5 registrations			

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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

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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