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 (8:30 am – 6:00 pm)

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

Brief Agenda:

- ✓ An Introduction to CORE Reference – How it Relates to Trial Transparency Initiatives
- ✓ CORE Reference – Practical Implementation in Writing
- ✓ Writing Lean and Balancing Scientific Accuracy
- ✓ Importance of Structured Authoring
- ✓ Exercises and Discussion

Convener: Rajesh Kher, Janssen

Chairperson: Shalini Dwivedi, Kinapse – a Syneos Health Company

Scientific Committee	Local Organizing Committee
Reema Bardhan, Eli Lilly	Ajay Pradhan (Janssen)
Payal Bharadwaj, TCS	Hitesh Manchanda, Kinapse – a Syneos Health Company
Hetal Shah, MeWriT	

Registration Details (Fees in INR)**:**

*ISCR is the sole sponsor of this event

		By 30 Sep 2019	Between 01 Oct 2019 – 30 Oct 2019	Registrations after 30 Oct 2019
Delegate Fees#	**ISCR Member**	**Rs. 2500/-**	**Rs. 3500/-**	**Rs. 4500/-**
	Non ISCR Member	**Rs. 3500/-**	**Rs. 4500/-**	**Rs. 5500/-**

 # Group registration discount: 1 registration 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 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 **Telephone:** +91-8454827775

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