



## **14<sup>th</sup> ISCR Annual Conference 2021**

### **Pre-Conference Workshop: 12-13 March 2021**

**Title: Effective authoring of clinical study reports (CSRs) in the evolving landscape of data transparency — *a competency building workshop***

**Date & Time: 12 March 2021, Friday; 12:00 hrs to 20:00 hrs.**

#### **Who should attend:**

Medical writers (all levels), regulatory writers (beginners & experienced), publication writers, scientific writers, study report writers, regulatory affairs specialists, clinical trial disclosure associates, research scholars, scientists, biostatisticians, data manager, 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 regulatory writing and clinical trials reporting.

#### **Description:**

A comprehensive clinical study report (CSR) that provides a ready-to-use complete and detailed representation of a study is a core document to clinical data sharing for the foreseeable future. Demands for greater openness in communicating clinical trial findings have fueled the introduction and evolution of data transparency and disclosure requirements in the pharmaceutical industry. Informed authoring of CSRs for clinical trials in current times require a thorough understanding of various mandatory and ever-evolving global and regional regulations; while striking the right balance between efficient writing for drug approvals and respecting proprietary information and study participants' privacy. Today's medical writers need an in-depth knowledge of results reporting and disclosure requirements; meticulous appreciation and understanding of the study details; consistent and inclusive presentation of the study results; and the ability to present complex trial data in formats for newly intended audiences beyond the regulators. This hands-on workshop intends to upskill the participants for the existing and futuristic CSR writing requirements, regulations governing CSR authoring; effective content presentation, and disclosing needs.



**Agenda:**

No.	Time*	Title*	Speaker
1.	12:00 – 12:15	Introductions and Objectives	Hetal Shah <i>Director, MeWriT Healthcare Consulting</i>
<b>Understanding the current scope of authoring CSRs</b>			
2.	12:15 – 13:15	<b>Keynote</b> Clinical study reports (CSRs) in the era of public disclosure: Current expectations and future implications	Sam Hamilton <i>Global Head, Medical and Regulatory Writing and Public Disclosure; Clinipace</i>
-----1 hr lunch break-----			
3.	14:15 – 15:05	Critical appraisal and practical implementation of existing guidances for authoring CSRs - <i>Includes exercise/interactive component</i>	Hetal Shah
4.	15:05 – 15:15	Live demonstrations to <a href="http://www.core-reference.org">www.core-reference.org</a>	Sam Hamilton
----- 15 min break-----			
<b>Effective content development</b>			
5.	15:30 – 16:45	Begin to write a clinical study report: Must-haves - <i>Includes exercise/interactive component</i>	Divya B. P. <i>Team Lead, Eli Lilly</i>
----- 15 min break-----			
6.	17:00 – 18:15	Comprehensive presentation of results – fit for purpose - <i>Includes exercise/interactive component</i>	Annie Jose <i>Medical Writing Specialist, Novonordisk</i>
----- 15 min break-----			
<b>Disclosure</b>			
7.	18:30 – 19:00	Secondary use of CSRs – disclosure perspectives - <i>Includes exercise/interactive component</i>	Jully Garg <i>Senior Medical Writer, Novonordisk</i>
8.	19:00 – 19:30	Writing plain language summaries (PLS) of CSRs – what should a medical writer know! - <i>Includes exercise/interactive component</i>	Annie Jose Jully Garg
9.	19:30 – 19:50	Troubleshooting techniques in CSR Writing – for medical writers by medical writers <b>Open Q/A Session</b>	All Speakers <i>Moderator: Hetal Shah</i>
10.	19:50 – 20:00	Closing Remarks & Vote of Thanks	Rajesh Kher <i>Director-Business Operations, Regulatory Medical Writing, Janssen</i>

\* Session time and details may vary slightly and will be updated in the final agenda.



**Convener/Annual Conference Scientific Committee Member:**

Dr. Rajesh Kher (Director - Business Operations, Regulatory Medical Writing; Janssen, India)

**Chairperson/Workshop Lead:**

Dr. Hetal Shah (Director; MeWriT Healthcare Consulting, India)

**Scientific Committee:**

- Dr. Samina Hamilton (Global Head, Medical and Regulatory Writing and Public Disclosure; Clinipace. Chair, CORE Reference Project. Based at UK)
- Annie Jose (Medical Writing Specialist - Clinical Reporting; Novonordisk, India)
- Divya B. P. (Team Lead - Medical Writing; Eli Lilly Services India Private Limited, India)
- Dr. Jully Garg (Senior Medical Writer - Clinical Transparency; Novonordisk, India)

**Registration details: Visit [www.iscr.org](http://www.iscr.org) – Annual Conference**

**Online Registration link - <https://www.iscr.org/iscr-conference-2021/#conference-and-pre-conference-workshops-online-registration>**

**Registration fees:**

	Students/Site Staff	Academia	ISCR/AMO Member	Non-Members
Pre-Conference Workshops	500	1000	1000	1000
Main Conference	500	1200	2000	3000

**Please feel free to write to [info@iscr.org](mailto:info@iscr.org) for any further information.**