



## Indian Society For Clinical Research

### Presents

**Virtual Conference Workshop on 23-24 July 2021, 10.00 hrs to 13.30 hrs**

### **Title: Science and Art of Simplifying the Complex scientific information in Plain Language Summaries**

**Highlights:** In the era of patient centricity, pharmaceutical industry is focused towards simplifying all the complex scientific information from clinical trials to make it more Patient Centric, so that the clinical trial participants can take informed decisions about their healthcare. The EU regulation 536/2014 mandates Biopharmaceutical companies to submit the “Plain Language Summaries (PLSs)” of clinical trial results, regardless of whether a product is approved for marketing or not. Plain language summaries are also known as lay summaries, lay language summaries, simple summaries, as they are targeted towards people with low to average health literacy and scientific understanding. The aim of Plain Language Summaries is to increase awareness about clinical research. These should not be used to make any healthcare decisions.

Scientific writers often face challenge on “WHAT” to consider when writing a Plain Language Summary and “HOW” to effectively address the needs of the target audience. The focus of this workshop is to train writers from various domains to effectively write the plain language summaries and meet the expectations of target audience while striking right balance of disclosure.

**Who should attend:** Medical Writers, Students, Academicians, Research Scholars, and Clinicians, Health and Patient education content writers.

**Convener:** Anushila Vaishali (Eli Lilly, India)

**Workshop Organizers:** Rajesh Pandey (Tata Consultancy Services) (Workshop Lead), Kishma Vinod (Bharat Serums & Vaccines Ltd), Neha Doshi (Cognizant), Jeevana CSS (Kinapse)

**Scientific Faculty:** Vidhi Vashisht (Kinapse) (Scientific Lead), Pooja Phogat (Kinapse), Sarita Desouza (TCS)



No.	Time*	Title*	Timing	Speakers
1.	10:00 – 10:15	<b>Introductions and Objectives</b>	15 minutes	Rajesh
<b>Day 1 – Topics</b>				
2.	10:15 – 10:45	<i>Overview of Plain Language Writing (Scope, Need in the industry, Target audience, Template overview, Sample PLS)</i>	30 minutes	Pooja
3.	10:45 – 11:15	Principles of Plain Language Writing <i>(Overview of Industry Resources for plain language writing, Harvard MRCT and NIH Guidelines, Language, Literacy, Numeracy)</i>	30 minutes	Sarita
4.	11:15 – 11:55	Writing the Trial Purpose in a PLS <i>(Three, one to show and two assignments)</i>	20 minutes+20 min exercise	Vidhi
----- 10 min break-----				
4.	12:05 – 12:45	Writing the Trial Results – Efficacy <i>(Three, one to show and two assignments)</i>	20 minutes+20 min exercise	Vidhi
6.	12:45 – 13:30	Introduction to Trial Drugs and Trial Participants <i>(One example to be included)</i>	20 minutes+15 min exercise	Sarita
<b>Close for the day</b>				Neha
<b>Day 2 – Topics</b>				
1	10-am to 10.10	<b>Introduction for Day 2 and Recap for Day 1</b>	10 minutes	Jeevana
2.	10:10 – 10:45	Writing the Trial Results- Safety	20 minutes +15 min exercise	Sarita
3.	10:45 – 11:15	Use of Visuals in Plain Language Summaries <i>(including Pie charts, graphs etc.)</i>	30 minutes	Vidhi
----- 10 min break-----				
4.	11:25 – 12:00	Exercise on Creating Visuals <i>(Trial Designs, Efficacy, Safety)</i>	35 minutes	Vidhi
5.	12:00 – 12:20	Readability Testing and Quality Check	20 minutes	Sarita
6.	12:20 – 12:40	- <i>Recap &amp; Key Takeaways</i>	20 minutes	Pooja
7.	12:40 – 13:20	- <i>Open Q&amp;A Hour (Addressing queries, doubts)</i>	40 minutes	Pooja, Vidhi Sarita
8.	13:20 – 13:30	<b>Closing Remarks &amp; Vote of Thanks</b>		Kishma Vinod



**Agenda:**

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

All registered participants will receive a “Certificate of Participation” from ISCR

**Registration fees:**

Registration fees (By 30 <sup>th</sup> June 2021)	Student / Academia – Rs. 400/-	ISCR Member – Rs. 750/-	Non ISCR Member – Rs. 1000/-
Registration fees (From 01 Jul 2021 onwards)	Student / Academia – Rs. 500/-	ISCR Member – Rs. 1000/-	Non ISCR Member – Rs. 1200/-

**Online Registration:** <https://www.iscr.org/events-registration/>

**Online Payment:** Once you will register for the event, you will receive payment link on your registered email id.

**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

**For any query, please write to: [info@iscr.org](mailto:info@iscr.org)**

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