Indian Society for Clinical Research Presents

Virtual Workshop on 27th -28th August 2021

Title: Authoring Clinical Study Protocols

Highlights: A scientifically-developed well-written clinical study protocol is vital for the smooth conduct of a clinical study. A clinical study that successfully ensures patient safety and evaluates drug efficacy is dependent on having a high-quality clinical study protocol, compliant with various regulatory guidelines. A well-developed clinical study protocol facilitates a smooth approval process by regulatory agencies, leading to a timely study start and conduct, and enabling the investigational medical product to swiftly reach the patients. The clinical study protocol development follows a collaborative process involving various contributing functions, highlighting the importance of team efforts and stakeholder management in developing this document.

The aim of this workshop is to train participants on the various aspects of protocol development for interventional global clinical trials. The intended audience include Medical Writers who are new or have minimal protocol writing experience, as well as any other participants that are involved or interested in the development of this regulatory document. At the end of the workshop the participants should have the skills to plan and develop a clinical study protocol.

Who should attend: Regulatory Medical Writers, Clinicians, Trial managers, and anyone who is involved in writing clinical study protocols. This workshop is also open to Publication Writers, Scientific Writers, Regulatory Affairs Specialists, Clinical Trial Investigators, Research Scholars, Scientists, 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 Clinical Research.

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

Workshop Organizers: Hannah Rajasingh (GSK) (Workshop Lead), Naimanulla Khan (IQVIA)(Workshop Co-Lead), Hetal Shah (MeWriT)

Scientific Faculty: Hannah Rajasingh (GSK), Naimanulla Khan (IQVIA), Prapti Bose (Eli Lilly), Kavita Muchandi (Parexel).

Workshop agenda:

The workshop will be virtual, interactive and activity-based!

		Day 1 – Friday August 27th 2021	
No.	**Time***	**Title***	**Speaker**
1.	11:00 – 11: 15 am	Welcome note and introduction	Hetal Shah
Overview of Clinical Study Protocols			
2.	11:20 am – 12:00 pm	Interventional Clinical Study Protocols – *an overview*	Hannah Rajasingh
3.	12.00 – 12.45pm	Guidelines, recommendations, and templates - *what regulatory authorities expect in a protocol* *(Including exercises/interactive activity)*	Kavita Muchandi, Naimanulla Khan
----------1 hour lunch break -------			
Building Blocks of Protocol Content Development			
4.	1.45 - 3.50 pm	Need for a concept sheet and protocol synopsis *(Including exercises/interactive activity)*	Prapti Bose
5.		Introduction - *setting-up the scientific background and rationale for the study*	Naimanulla Khan
6.		Study objectives -*focusing on aims of the study* *(Including exercises/interactive activity)*	Kavita Muchandi
		---------- 10 min break----------	
7.		Study design and schema - *what to keep in mind* *(Including exercises/interactive activity)*	Prapti Bose
8.		Schedule of activities/assessments- *critical for data collection and study integrity* *(Including exercises/interactive activity)*	Naimanulla Khan
9.	3.50 – 4:00 pm	Day 1 Summary and wrap-up	Hannah Rajasingh

		Day 2 – Saturday August 28th 2021	
No.	**Time***	**Title***	**Speaker**
1.	11:00 -11:10 am	Welcome and re-cap of Day 1	Naimanulla Khan
Building Blocks of Protocol Content Development [*continued]*			
2.	11.10 am – 1 pm	Study population - *general considerations* (*Including exercises/interactive activity*)	Prapti Bose
3.		Study interventions – *focusing on treatments and therapies*	Hannah Rajasingh
4.		Discontinuation of study intervention and withdrawal of participants	Kavita Muchandi
		---------- *10 min break*----------	
5.		Study assessments – *efficacy and safety* (*Including exercises/interactive activity)*	Kavita Muchandi
6.		Statistical considerations - *statistical analysis of endpoints assessments*	Naimanulla Khan
----------*1 hour lunch break* -------			
Protocol Writing Tips and Tricks			
7.	2.00 - 2.30 pm	Points to keep in mind while writing a protocol *(Including exercises/interactive activity)*	Kavita Muchandi
8.	2.30 - 2.50 pm	Roles and responsibilities involved in developing a protocol - *who does what* *(Including exercises/interactive activity)*	Hannah Rajasingh
---------- *10 min break*----------			
Process and Timeline			
9.	3.00 -3.25 pm	Process and timelines - *how to ensure you have a good protocol draft*	Prapti Bose

		(Including exercises/interactive activity)	
10.	3.25 – 3.55 pm	Open Hour: Q/A Session	All
11.	3.55 -4.00 pm	Vote of Thanks and closing remarks	Anushila Vaishali

All registered participants will receive a "Certificate of Participation" from ISCR

Registration fees (By 15th July 2021)	**Student / Academia – Rs. 500/-**	**ISCR Member – Rs. 1000/-**	**Non-ISCR Member – Rs. 1200/-**
Registration fees (After 15th July 2021)	**Student / Academia – Rs. 750/-**	**ISCR Member – Rs. 1200/-**	**Non-ISCR Member – Rs. 1500/-**

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 favour 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

For any query, please write to: info@iscr.org
Indian Society for Clinical Research
The Capital, 1802, 18th Floor, Plot No. C- 70,'G' Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051 **Contact No (Office): +**91-8454827775
Email:info@iscr.org **Website**: www.iscr.org