Indian Society for Clinical Research Presents

Virtual Workshop on 22nd – 23rd September 2022

Title: Clinical Trial Protocols – From Templates to Trending Topics

Highlights: The clinical trial protocol is one of the most important regulatory documents in clinical research. Different protocol templates exist that serve different purposes during drug development. In the current era of automation, protocol development can be optimized through use of eProtocol applications, closely interlinked with the use of specific protocol libraries and master protocols. Navigating through EU CTR regulations and assessing the impact of the COVID-19 pandemic and beyond; medical writers need to be agile and require strong leadership skills to influence, lead, manage change and promote lean writing practices during protocol writing. Not only does a medical writer develop a protocol, but the protocol develops the medical writer.

The aim of this interactive workshop is to discuss pertinent themes related to the clinical trial protocol. The intended audience includes medical writers who already have experience in protocol writing, as well as any other participants who are involved or interested in the development of this regulatory document. At the end of the workshop the participants should understand the forms of protocols in development, the growing need for the medical writer to be agile and adapt in an ever-changing- environment of regulations, and skills that can be developed and fine-tuned on the protocol writer journey.

Who should attend: Regulatory medical writers, clinicians, trial managers, and anyone who is involved in writing clinical trial 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: Anick Vandingenen (Janssen), Hanalie Van Passel (Janssen), Marjan Moreels (Janssen), Vinod Singh (TCS).

Scientific Faculty: Anick Vandingenen (Janssen), Hanalie Van Passel (Janssen), Binutha Pereira (Eli Lilly), Agila Uma Subramaniam (Parexel), Deepthi Sathyajith (Parexel), Ankit Shah (Eli Lilly), Senyo Ofori (Janssen), Tatiana Piotroff (Janssen), Charu Misra (Janssen), Vaishali Kerekatte (Parexel).

Workshop agenda:

The workshop will be virtual and interactive!

Clinical Trial Protocols – From Templates to Trending Topics				
Day 1 - Protocol Templates and Libraries				
Title	**Duration**	**Time (IST)**	**Speaker**	**Topics Covered**
Welcome and Introduction	15 minutes	4:00 – 4:15 pm	Host: Anick Vandingenen	- Scope of the workshop - Agenda - Introduction of speakers & host - Logistics
Types of Protocol Templates During Drug Development				
Protocols in Drug Development	45 minutes	4:15 – 5:00 pm	Malavika Bondal	- Discuss how different protocol types come into play during drug development - Common Protocol Template (CPT) and uses in interventional protocols - Real World Evidence and Non-Interventional Study protocols
Navigating Changing Guidance and Regulations				
EU CTR - Impact on protocol amendments	30 minutes	5:00 – 5:30 pm	Sonika Mehra & Richard Exley	Country-specific protocol amendments in view of EU-CTR, EU and US perspective
Break	10 minutes	5:30 – 5:40 pm		
Protocol Libraries and eProtocol Efficiencies				
- Industry benchmark – origin and purpose - Synergies/efficiencies with the eProtocol	20 minutes	5:40 – 6:00 pm	Tanuja Rohatgi & Emily Santaniello	- Overview of libraries and benchmark to industry - Purpose of eProtocol and efficient library use

Oncology Library				
Challenges and Considerations for Oncology Studies	20 minutes	6:00 – 6:20 pm	Alfred Delvecchio	- Overview of different types of oncology studies - Overview of different types of agents used in oncology studies
Vaccine Library				
How does a prophylactic vaccine protocol differ, e.g, from a therapeutic drug protocol?	25 minutes	6:20 – 6:45 pm	Anick Vandingenen	- Introduction to vaccine-specific language - Exercise to take back home and think about for Day 2
Panel Discussion				
Clinical Trial Protocol Efficiencies – Industry Perspectives	40 minutes	6:45 – 7:25 pm	Ankit Shah, Richard Exley, Vaishali Kerekatte, Charu Misra	Our trials are getting more and more complex, and the industry continues to search for leaner and more harmonized ways of conducting clinical studies. The topics we present at the conference address new approaches that increase efficiency in the study protocol development. The proposed questions for the panel discussion may further accentuate the role of these new modalities and elicit further insights about potential benefits.
Open House				
- Open house Q&A - Wrap up for Day 1	20 minutes	7:25 – 7:45 pm	Host/all speakers Day 1	- Q&A - Wrap Up and link to Day 2

Day 2 – Protocol Topics of Interest – 23 Sep 2022				
Title	**Duration**	**Time**	**Speaker**	**Scope**
Welcome and introduction	15 minutes	4:00 – 4:15 pm	Host: Hanalie Van Passel	- Recap of Day 1 and purpose (by host of Day 1) - Agenda Day 2 - Introduction of speakers & host - Logistics
Exercise feedback – Vaccine Library				
Discussion on exercise of Day 1	20 minutes	4:15 – 4:35 pm	Anick Vandingenen	- Discussion on answers of the exercise - Feedback from participants
Platform Programs				
Master protocols	20 minutes	4:35 – 4:55 pm	Hanalie Van Passel	- Understanding master protocols - Potential benefits - Lessons learned - The master protocol template
Adapting the Protocol During COVID-19				
Clinical Trial Protocol evolution during the COVID-19 pandemic	25 minutes	4:55 – 5:20 pm	Senyo Ofori	- Overview of how the approach was adapted to align with regulatory guidance, and changing therapeutic area needs. - Evolution from COVID-19 focused wording to general major disaster wording - Exercise on how to adapt protocol assessments during a major disruption
Protocol Quality and Medical Writer Development				
Role of medical writer in protocol concept sheet development	25 minutes	5:20 – 5:45 pm	Binutha Pereira	- Overview of concept sheet - Essential components - Key players - Best practices

Break	10 minutes	5.45 – 5.55 pm		
Critical role of medical writer's skillset in protocol development	50 minutes	5:55 – 6:45 pm	Jenna Cook & Tatiana Piotroff	The protocol is one of the most important and unique regulatory document type. This topic will illustrate the key role of the medical writer in influencing, leading, managing change and promoting lean writing practices during protocol development. Key questions that will be discussed in this interactive session include: - What makes a protocol "well-written"? - What leadership skills are necessary for the long-term growth of a writer?
Metrics and related indicators in Protocol Writing	30 minutes	6:45 – 7:15 pm	Agila Uma Subramaniam & Deepthi Sathyajith	This presentation will detail the importance of getting the timelines right first-time. The presenters will also discuss protocol amendments and their relative occurrence during the lifetime of a clinical study as well as the importance of expert opinion and when to take a step back.
Open House				
- Open house Q&A - Wrap up for Day 1 and Day 2	30 minutes	7:15 – 7:45 pm	Host/all speakers Day 1 and Day 2	- Q&A - Wrap Up

Online Registration: https://www.iscr.org/Upcoming_Events.aspx

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

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