Indian Society of Clinical Research Presents

Virtual Conference Workshop on 13-14 August 2021

Title: Managing Clinical Evaluation, Clinical Performance and Safety of Medical Device

Highlights: The development and approval of medical devices differ from those of new drugs or biologics. The inherent difference between medical devices and drugs have implications for clinical research, safety assessment, and regulatory submission. The adoption of new European Union (EU) Medical Device Regulation (MDR), have changed the legal framework for medical devices across EU and the globe as they pose many new questions and challenges for the medical device industry. A clinical evaluation is required to verify the safety and performance of a medical device, including its clinical benefits during pre-market approval while a postmarket surveillance (PMS) to collect, record, and analyze relevant data on the quality, performance, and safety of a device throughout its lifetime to determine, implement, and monitor any corrective and preventive actions. In addition, a system for risk management is required to minimize risks or prevent incidents related to medical devices along with field safety corrective actions. The new MDR requires a PMS plan, report and a Periodic Safety Update Report for medical devices, which is a relatively new concept.

This virtual workshop will be focus on generating clinical evidence, managing the safety of medical devices during pre- and postmarket approval, and discuss key consideration for the benefit-risk assessment of medical devices throughout their lifecycle.

Who should attend: Medical Writers, Drug and Device Safety Scientists, Clinical Researchers, Medical and Regulatory Affairs Professionals, Students, and Academicians

Workshop Organizer: Bindu Narang (Labcorp Drug Development)

Taskforce Committee: Ashish Indani (TCS), Sundeep Agarwal (Datt MediProducts Pvt. Ltd.), Priyadarshini Arambam (Batra Hospital)

Agenda:

No.	Time*	Title*	Timing	Speaker
1	1.30 -1.45 pm	Introductions and Objectives	15 min	Bindu Narang- Labcorp Drug Development
		Day 1 – Topics		
2	1.45-2.30 pm	Demystifying the World of Clinical Research in Medical Devices	45 min	Ashish Indani-TCS
3	2.30 -3.15 pm	Clinical Evidence by Clinical Experience and Equivalence	45 min	Sundeep Agarwal- Datt MediProducts Pvt. Ltd.
		---------- 15 min break----------		
4	3.30 -4.15 pm	Clinical Investigation for Medical devices - Managing the Critical Elements	45 min	Vinay Rajan- Medtronic
5	4.15 -5.00 pm	Monitoring and Reporting of Safety of Medical Devices During Clinical Investigation	45 min	Mamta Vashishth- Labcorp Drug Development
6	5.00 -5.45 pm	Overview of Postmarketing Surveillance Plans for Medical Devices	45 min	Erica Schirmer - Johnson & Johnson Consumer Inc.
		Day 2 – Topics		
7	1.30 -2.15 pm	Medical Device Vigilance - Digital Forces to Manage Complex Safety Outcomes for Patient, Device Users and Others	45 min	Ranjana Banerjee-TCS
8	2.15-3.00 pm	Clinical Evaluation Reports: A Medical Writer's Perspective	45 min	Sowjanya Jaladi-HCL
		---------- 10 min break----------		
9	3.15-4.00 pm	Performance Evaluation (Scientific Validity, Analytical and Clinical Performance) for Diagnostics Devices - EU IVDR	45 min	Lakshman Balajepalli, Huwel Lifesciences Pvt Ltd.
10	4.00-4.15 pm	Key Consideration for Benefit-Risk Assessment and Risk Management of Medical Devices	45 min	Can Ozkan- Labcorp Drug Development
11	4:15 – 5:00 pm	Panel Discussion: Impact of new MDR/IVDR Regulations on Registrations and Lifecycle Management of Medical Devices	45 min	Moderator: Rajendra Wable, Labcorp Drug Development Ashish Indani -TCS Praveen Kumar Kumar-Cipla Priyadarshini Arambam - Batra hospital Alejandra Guorchicoff – TCS
12	5.00- 5.15pm	**Closing Remarks and Vote of Thanks**	10 min	Rajendra Wable, Labcorp Drug Development

** 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 (By 25th July 2021)	**Student / Academia – Rs. 500/-**	**ISCR Member – Rs. 1000/-**	**Non ISCR Member – Rs. 1200/-**
Registration fees (After 25th 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 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

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