Indian Society for Clinical Research Presents

Virtual Workshop on 04 and 05 November 2022

Title: Overview of Aggregate Reports-Classification, Significance, and Industry Challenges

Highlights: Pharmacovigilance is defined as the "science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem". Aggregate reports or safety reports such as Periodic Adverse Drug Experience Reports (PADERs), Periodic Benefit Risk Evaluation Reports (PBRERs), Development Safety Update Reports (DSURs), and Risk Management Plans (RMPs) play an important role in the assessment of benefit-risk profile of a drug.

The aim of this workshop is to provide an overview of development of aggregate reports, discuss best practices, and project management tips. The intended audience include Medical Writers who are new or have aggregate report writing experience, as well as any other participants that are involved or interested in the development of aggregate reports.

Who should attend: Regulatory Medical Writers from pharmaceutical industry and contract research organizations. This workshop is also open to Publication Writers and Scientific Writers 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.

Workshop Organizers: Asha Mathew Liju (Parexel) (Workshop Lead), Rajneeta Roy (Eli Lilly) (Workshop Co-Lead), Sabika Rizvi (IQVIA), and Navneet Sonawane (LabCorp).

Scientific Faculty:
Bindu Narang (LabCorp), Nalin Taneja (Parexel), Vinay Dubey (Syneos), Farzana Banu (Parexel), Rupesh Thorat (SIRO), Ashish Adgaonkar (Novartis), Rajneeta Roy (Eli Lilly), Sivanandan Sivaraj (AZ), Darshil Panchal (IQVIA), Navneet Sonawane (LabCorp).

Convener: Anushila Vaishali (Eli Lilly)

Workshop Agenda:

Topics	Duration (in hour)	Start Time – End Time (IST)	Speaker
DAY 1: 04 Nov 2022, Friday (10 am to 4:30 pm)			
Introduction to conference theme	0.25	10:00 am to 10:15 am	Moderator
Keynote address	0.75	10:15 am to 11:00 am	Bindu Narang
PADERs/PAERs	1.5	11:00 am to 12:30 pm	Nalin Taneja and Vinay Dubey
Commonly used terms			
Regulatory expectations - What does the FDA require?			
Authoring a PADER/PAER			
Significance of safety conclusion			
Points to consider during authoring/before submission			
Ambiguity of requirements and variations in authoring safety sections			
Expectations and challenges			
Managing large portfolios and high volumes			
Q&A	0.25	12:30 pm to 12:45 pm	Moderator
LUNCH BREAK (12:45 to 1:15 pm)			
Post-lunch opening note	0.25	1:15 pm to 1:30 pm	Moderator
DSURs and PBRERs	2.5	1:30 pm to 4:00 pm	Rupesh Thorat and Farzana Banu
DSUR overview and regulatory guidance implementation strategies			
Decoding PBRER authoring			
Harmonization of data across DSURs and PBRERs			
Q&A	0.25	4:00 pm to 4:15 pm	Moderator
Day 1: Wrap-up summary	0.25	4:15 pm to 4:30 pm	Moderator

DAY 2: 05 Nov 2022, Saturday (10 am to 5:00 pm)			
Opening note	0.25	10:00 am to 10:15 am	Moderator
RMPs Overview of RMPs – Understanding its importance and requirements Key concepts EU and local RMPs Writing RMPs (with focus on EU RMPs) – Best Practices	2.5	10:15 am to 12:45 pm	Rajneeta and Ashish Adgaonkar
Q&A	0.25	12:45 to 1:00 pm	Moderator
LUNCH BREAK (1:00 pm to 1:30 pm)			
Post-lunch opening note	0.25	1:30 pm to 1:45 pm	Moderator
General topics and panel discussion			
Impact of EU CTR Regulation (EU) 536/2014 on aggregate reports	0.5	1:45 pm to 2:15 pm	Sivanandan Sivaraj
Understanding nuances of benefit risk assessment for aggregate reports	0.75	2:15 pm to 3:00 pm	Darshil Panchal
Development of Aggregate Reports - Project Management Tips and Best Practices	0.75	3:00 pm to 3:45 pm	Navneet Sonawane
Panel Discussion **Topic:** Aggregate Reports – Discussion around Industry Challenges and Proposed Solutions	0.75	3:45 pm to 4:30 pm	**Panel Lead:** Sabika Rizvi **Panel members:** Sherin Babykutty (Eli Lily), Kavita Sharma (TCS), Deepmala Madaan (IQVIA), Sneha Salgar (Parexel), Raghuram Chimata (LabCorp)
Closing remarks	0.25	4:30 pm to 4:45 pm	Moderator

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

Registration fees (By 30th Sep 2022)	**Student / Academia – Rs. 500/-**	**ISCR Member – Rs. 1000/-**	**Non-ISCR Member – Rs. 1200/-**
Registration fees (After 30th Sep 2022)	**Student / Academia – Rs. 750/-**	**ISCR Member – Rs. 1200/-**	**Non-ISCR Member – Rs. 1500/-**

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

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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