Indian Society for Clinical Research Virtual Conference
Title: Connecting Global Regulatory Submission Strategy and CTD Components

10 Dec 2021, Friday (12:30 to 4:30 pm)
11 Dec 2021, Saturday (10:00 am to 2:30 pm)

Conference Objective

This conference will provide attendees an overview of the required clinical documentation for a marketing authorisation application (MAA), explain and identify the principles of clinical development from phase I to IV, and explain and discuss how to create, analyze, and evaluate a regulatory strategy plan for the clinical development of a new medicinal product. At the end you will be able to appreciate and understand a compound/molecule's journey from the initial clinical development plan to the desired label.

Who should attend?

Regulatory Medical Writers from pharmaceutical industry and contract research organizations with experience in writing clinical study reports and submission-level documents. This conference is also open to regulatory medical writers who are aspiring to

work on submission-level documents and to those who are interested to know the regulatory strategy plan behind clinical development of a new medicinal product.

Conference organizers: Garima Pallavi (Parexel), Shruti Mp (Parexel), Saurabh Singh (Novartis), Priyanka Bhattacharya (Roche), Annie Jose (GSK), Meenakshi Mudiraj (Eli Lilly), and Asha Mathew Liju (Parexel).

AGENDA				
No.	**START TIME – END TIME**	**TITLE**	**DURATION**	**SPEAKER**
DAY 1				
1	12:30 – 12:40 pm	Introduction to workshop theme	10 mins	Saurabh Singh
2	12:40 – 1:25 pm	**Keynote address: The importance of assessing the regulatory landscape and speed to market when determining your regulatory strategy.** ✓ Understanding regulatory requirements in targeted markets - e.g., clinical trials/local patients, regulatory guidelines, regulatory precedents (review labels and public assessment reports) ✓ Use of expedited pathways in each region – which ones will work for your product ✓ Knowing the current clinical practice in each region (clinical guidelines and competitor products) ✓ Understanding the regulator and payer perspective on your clinical development in particular the pivotal study(ies) (seek input from Regulators before pivotal study also HTAs) (note	45 mins	Bridget Heelan, Vice President, Regulatory Consulting, Parexel

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		HTAs can delay launch after approval in EU)		
3	1:25 – 2:05 pm 2:05 – 2:50 pm	**Labelling as a Driver for Regulatory Strategy** ✓ The why – what – who- when of regulatory strategy- get your message through! ✓ Why strategy is important? What is involved in developing a strategy?	45 mins each	✓ Ravikant Bhatia, Expert Regulatory Writer, Regulatory Writing and Submissions, Novartis ✓ Shakti Ranjan Rath, Senior Regulatory Writer, Regulatory Writing and Submissions, Novartis
4	2:50 – 3:00 pm	Q&A	10 mins	Garima Pallavi
BREAK (3:00 to 3:15 pm)				
	3:15 – 3:45 pm 3:45 – 4:15 pm	**Clinical Study Reports – The building blocks in a submission** ✓ Different types of CSRs in a submission package ✓ Where do CSRs fit in the big picture?	30 mins each topic	✓ Tarang Shah, Senior Medical Writer, IQVIA ✓ Manasa Ravishankar, Principal Medical Writer, Parexel
	4:15 – 4:25 pm	Q&A	10 mins	Garima Pallavi
	4:25 – 4:30 pm	**Wrap-up summary by the Moderator:** ✓ Summary from Day 1 ✓ Vote of thanks	5 mins	Saurabh Singh

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No.	**START TIME – END TIME**	**TITLE**	**DURATION**	**SPEAKER**
DAY 2				
	10:00 – 10: 05 am	Opening note by Moderator (Agenda for the day - also connecting Day 1)	5 mins	Meenakshi Mudiraj
	10:05 – 10:50 am 10:50 – 11:35 am	**Summary documents -** ✓ Overview of CTD modules ✓ Strategy-driven development of clinical modules	45 mins each topic	✓ Yoganand Kumar Duppalapudi, Group Leader, GBS Lilly Capability Center India, Eli Lilly and Company ✓ Annie Jose, India Function Manager, GSK
	11:35 am – 11:50 pm	Quiz	15 min	Meenakshi Mudiraj
	11:50 – 12: 00 pm	Q&A	10 mins	Shruti Mp
BREAK (12:00 to 12:30 pm)				

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No.	**START TIME – END TIME**	**TITLE**	**DURATION**	**SPEAKER**
	12:30 – 1:00 pm 1:00 – 1:30 pm	**Unifying message across all documents leading up to the label** ✓ Strategic/Key Messaging methodology ✓ Managing messages across documents	30 mins each	✓ Baharul Islam, Expert Regulatory Writer, Regulatory Writing and Submissions, Novartis ✓ Manoj Kumar Subbaiah, Expert Regulatory Writer, Regulatory Writing and Submissions, Novartis
	1:30 to 1:40 pm	**Q&A**	10 mins	Shruti Mp
	1:40 to 2:10 pm	Panel discussion	30 mins	Asha Mathew Liju
	2:10 to 2:20 pm	Closing remarks	10 mins	Priyanka Bhattacharya

** 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	Student / Academia	ISCR Member	Non ISCR Member
By 20th Nov 2021	Rs. 500/-	Rs. 1000/-	Rs. 1200/-
After 20th Nov 2021	Rs. 750/-	Rs. 1200/-	Rs. 1500/-

Online Registration: https://www.iscr.org/Upcoming_Events.aspx
Online Payment: Once you will complete the registration, you will receive payment details along with the confirmation email 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

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