Indian Society for Clinical Research

presents Virtual Symposium on

Submission standards for various Health Authorities for Statisticians & Statistical Programmers

2rd Dec 2022, 14:00 (IST) - 17:45 (IST)

Highlights:

Drug application submissions at global regulatory agencies such as the FDA, EMA, PMDA, NMPA and DCGI require well-defined data standards following the CDISC SDTM and ADaM specifications. In many companies, Biostatistics and statistical programming functions have become the data hub and provide regulatory-compliant data packages following these formats

The submission requirements vary across the regulatory agencies. It is more important for a Statistician or Statistical Programmer to understand the requirements and fulfill. This workshop is going to explore data submission package requirements for various global regulatory bodies. This four-hour workshop is designed to enable and explore the participants to gain more insights on submission requirements and differences between the agency's requirements from Statistician's & statistical programmers' perspective.

Who should attend: Data Scientists, Statistical Programmers working with Pharmaceutical Industry or Contract Research Organizations, Biostatisticians, Medical Writers, Clinical Scientists, Clinical Data Managers, Investigators, Research Scholars or Scientists interested in Clinical Research, HealthCare Professionals from Government Agencies, Non-profit Organizations/Associations and Academia, and Medical, Pharmacy, Statistics or Life-science Students or Professionals interested in Clinical Research.

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

Convener: **Gaurab Chakraborty** (Labcorp)

Event Organizers: **Pramod Reddy** (Dr. Reddy's) (Event Lead), **Deepak Venkataraman** (Eli Lilly), **Krishnendu Biswas** (Novartis), **Hanumantha Rao Karedla** (Bayer), **Neha Srivastava** (Labcorp), **Smitha Nalam** (ICON), **Pinakin Jani** (IQVIA), **Anadya Prakash Tripathi** (Abbott), **Pankaj Tiwari** (GSK), **Deepthi Porumalla** (SIRO Clinpharm)

Agenda

No.	Time (IST)	Title	Speaker
1.	14:00 – 14:10	**Introduction & Welcome Note**	**Pramod Reddy** **Head, Data management and Biostatistics, Dr. Reddy's, India**
2.	14:10 – 14:50	**Essential knowledge for PMDA submission - From eData requirements to inspection and HAQ after NDA**	**Nakajima Yuichi and Hasegawa Jun** **Novartis, Japan**
3.	14:50 – 15:30	**eData Submission to NMPA in China**	**Derek Li** **Bayer, China**
---------- 15 mins break----------			
4.	15:45 – 16:25	**Overview of EMA Requirements**	**Margrete Due Thomsen,** **Novo Nordisk**
5.	16:25 – 17:05	**FDA Submission for COVID Emergency Use Authorization**	**Jack Knorr** **Lilly, USA**
6.	17:05 – 17:35	**How much do we know about Indian submissions**	**Shivani Dharwadkar** **Bayer, India**
10.	17:35 – 17:45	**Closing Remarks**	**Hanumantha Rao Karedla** **Head, Oncology Data Analytics, Bayer, India**

Registration fees	Student / Academia – Rs. 500/-	ISCR Member – Rs. 750/-	Non ISCR Member – Rs. 1000/-

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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