INDIAN ASSOCIATION FOR STATISTICS IN CLINICAL TRIALS (IASCT)

"Deep dive into Regulatory Submissions – Role of a Programmer and Statistician"

IASCT
Indian Association for Statistics in Clinical Trials
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Friday, October 18
9:00 AM—5:00 PM at Pune

ABOUT THE WORKSHOP

Regulatory submissions are very important milestones for pharmaceutical organizations/sponsors post completion of analysis and reporting of any clinical trial that documents the safety and efficacy data of their new innovative medicinal products. In order to accelerate and shorten the time from lab to market and bring clinical benefits to patients faster, while ensuring patient safety and optimizing research investments, we require quality regulatory submissions. This would also speed up regulatory agencies' review, evaluation and approval of new products. eCTD (electronic Common Technical Document) is a standard required format to submit all the clinical research and development data of a new investigational product to the Health Authorities. In addition to individual clinical study reports, sponsors require to pool safety and efficacy data from individual clinical studies, prepare, and submit Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) reports into CTD for product benefit-risk evaluation. After a regulatory submission, there are usually Health Authority Questions (HAQs) on data and sponsors may need to explore/investigate individual or pooled study data, reports and provide responses quickly back to the HA. After review of submitted dossier, the HA may decide to further evaluate the product through Advisory Committee (AdCom) meeting discussions before their decision on product approval. Sponsors may have to prepare additional exploratory analyses for any potential questions from the AdCom meetings.

This workshop will aim to discuss various statistical activities required for regulatory submissions in multiple therapeutic/disease areas with case studies/examples, including roles and responsibilities of statisticians and statistical programmers. This will also delve into common challenges in planning and generating the reports including electronic submission requirement per CDISC compliance.

SPEAKERS

Tejaswini Jalikop,
Syneos Health

Suresh Chenji,
Syneos Health

For more details visit http://www.iasct.net/

Registrations Open

18th October, 2019

Pune, India

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About the speakers

Tejaswini Jalikop

Tejaswini is working as Manager, Biostatistics at Syneos Health and has around 12 years' of industry experience. She has been with Syneos Health for 8.5 years and previously with a sponsor organization for more than 3 years. She has worked as a trial statistician and has experience working as a lead statistician on a number of trials and has worked on tasks such as: Providing inputs to study protocols, eCRF review, preparation of SAP, mock shell creation, statistical review of ADS and TFLs, Clinical Study Report, publications. She has also supported regulatory submissions and has experience in providing responses to regulatory questions. She is currently managing a team of statisticians in India for various FSPs along and is also involved in trials as a lead statistician and Senior reviewer for the team.

Suresh Chenji

Suresh is working as Associate Director, Biostatistics at Syneos Health, with 18 years' experience in a variety of positions within CROs, the pharmaceutical sector and academia. Suresh has managed large groups of statisticians and has supported study design, regulatory submissions, integrated summaries, publications pricing and project management. He currently heads the team of Statisticians in India on Full Service projects and serves as senior reviewer for team critical project deliverables.

Time	Agenda
9:00 - 9:30	Registration/arriving at the venue
9:30 - 11:00	➢ Clinical development of new products and Regulatory submissions ➢ New products data documentation for regulatory submissions – eCTD ➢ Integrated Summary of Safety and Efficacy (ISS/SCS and ISE/SCE) and Meta-Analysis in Regulatory Setting
11:00 - 11:15	Tea/Coffee break
11:15 - 13:00	➢ Exploratory analysis for response to HAQs and AdCom ➢ Statistical Programming challenges during submission preparation and regulatory review ➢ Study Data Standards Quality and Electronic format for Regulatory Submissions
13:00 - 14:00	Lunch break
14:00 - 15:00	➢ Statistical topics/issues in review and approval process of regulatory submissions
15:00 - 15:15	Tea/coffee break
15:15 - 16:30	➢ Recent Innovative Approaches and Regulatory Submission/Review (Adaptive Designs, Biosimilars, Master Protocols, Pragmatics Trials& RWD/E, etc.,.) ➢ Roles and Responsibilities of Statistical Programmer and Biostatistician
16:30 - 17:00	➢ Workshop Summary

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