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Statistical Challenges in Pharmaceutical Industry

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There is a common perception that bringing in statistical innovation in the highly regulated industry, such as pharmaceutical companies, is a hard mission. Often, due to legal constraints, the statistical innovation in the nonclinical space is not obvious to the outer world. In our discussion panel we would like to discuss challenges we face as industrial statisticians working in pharmaceutical companies and the main focus would be automation of the statistical analyses and workflows in our practice. Automation can on one hand free up statistical practitioners to focus more on bringing in innovative approaches rather than rerunning routine/repeatable analyses and standard reports, on the other hand, help to provide access to novel tools for data exploration and analysis.

We shall talk what types of analyses does it usually make sense to automate, share the successful automation story and lessons learned from the automation tools which were more failures. Bayesian framework will also be discussed with its benefits and challenges. The prior information requires a thoughtful cross-disciplinary discussion to empower the analyses. We would also like to bring to a broader audience strategies which make automated tools widely adopted, i.e. via trainings, good agreements and collaborations with stakeholders. In addition, technical aspects of software implementation would be brought up, such as data format requirements, ensuring reproducibility of the analysis etc. Finally, a set-up of highly regulated analyses (i.e. Good Manufacturing practices) vs. exploratory ones (in early development) requires specific approach and rigor to ensure the final software or script would be applied for the developed purpose and would be a good return on invested time and resources.

The panel discussion would also contain some example case studies from several companies the panelists represent.

Type of presentation

Talk

Classification

Both methodology and application

Keywords

statistical innovation, pharmaceutical companies, automation, validation, statistical trainings

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Session Classification: Invited session: Statistical challenges in pharmaceutical industry