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Bayesian Statistics in Pharmaceutical R & D & Manufacturing

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In the pharmaceutical industry, the use of statistics has been largely driven by clinical development, an area where frequentist statistics have been and remain dominant. This approach has led to numerous successes when considering the various effective treatments available to patients today.
However, over time, Null Hypothesis Significance Testing (NHST) and related Type-I error thinking became almost the exclusive method for handling statistical questions across all aspects of the pharmaceutical industry - in discovery, preclinical/translational research, and even in manufacturing - well beyond confirmatory Phase III trials. This has often resulted in adapting and twisting questions and answers to fit the NHST framework, rather than applying appropriate statistical methodologies to the specific questions at hand and fully understanding the impact of the solutions provided.
In my talk, I will first provide examples from preclinical research and manufacturing where, in some cases, a frequentist approach is appropriate, while in others, Bayesian statistics is more oriented towards the question of interest.
Secondly, I will explain how, over the last 20 years, I have been working to organize the sharing of case studies using Bayesian statistics, spread applied knowledge, and promote the careful but necessary acceptance of Bayesian methodology by both the statistical community and regulatory authorities.

Type of presentation

Talk

Classification

Mainly application

Keywords

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