Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 24. November 2020, 17:00 – 18:30 Uhr

Wo: Online

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Statistical issues in drug development - The role of statisticians in regulatory agencies

Drug development is a difficult, time-consuming and expensive task with many challenges and pitfalls. One starts with early preclinical trials to assess toxicity, pharmacokinetics and first signs of efficacy in non-human subjects. After a successful preclinical development program, pharmaceutical companies or research consortia conduct a series of clinical trials in humans from Phase I (safety, dose finding) to Phase III (confirmatory proof of efficacy). These data are submitted to regulatory agencies (e.g. the EMA or national agencies in Europe) to be granted market access. The talk will show that drug development is also a challenging task for regulators who need to keep pace with the pharmaceutical industry in order to be able to talk to companies at eye level and to appropriately and timely assess submitted documents.
To set the current practice into perspective, this talk will begin with an historical overview on drug development and drug regulation with a special focus on statistics: With randomized controlled clinical trials evolving since the late 1940s many of the current standards quite modern. Only since 1976, a proof of efficacy was needed to gain market access in Germany.
The different roles of the European Medicines Agency (EMA) and national agencies (here the Paul-Ehrlich-Institut; PEI), will be illustrated and regulatory procedures especially marketing authorization applications will be briefly explained. The special role of statisticians in the regulatory system will be of particular interest throughout the talk.
The talk will end with a brief overview of current hot topics in regulatory statistics.