

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 16. Dezember 2014, 17:00 – 18:30 Uhr

Wo: Lebenswissenschaftliche Fakultät, Humboldt-Universität zu Berlin,
Hörsaal 2, 2. Etage, Invalidenstr. 42, 10115 Berlin

Joachim Röhmel (Bremen)

Ein neuer nichtparametrischer Ansatz für Tests auf Heterogenität von Ergebnissen in Untergruppen klinischer Studien.

Thirty years ago multi-center trials had been a big methodological challenge. Today such trials are perceived as something quite normal and the focus has shifted towards multi-regional studies. Geographical regions can have very different culture, standards, norms and traditions. This clearly impacts many parts of clinical studies' conduct. Main areas where strong differences are sometimes visible are patient information, informed consent, handling of inclusion and exclusion criteria. More importantly these inter regional differences can also influence clinical monitoring and the assessment of primary and secondary endpoints. This can result in considerable heterogeneity and can raise suspicions about the usefulness of clinical trial data generated in a foreign region.

In clinical trials test for homogeneity/heterogeneity are often requested by regulatory authorities and also by health economists. There are some characteristics that are regularly investigated for heterogeneity: gender, age, severity of disease and geographical region. However, at present no unifying approach has been developed and handling of heterogeneity varies between national health services and can lead to compromising a complete study program. Some recent examples will be discussed.

For the investigation of homogeneity/heterogeneity Cochran's Q statistic is often applied. In the second part of my talk I argue that the research area may benefit from development of further techniques, and I present new tests for various discrepancy measures based on generalizations of Zelen's conditional approach.