Kolloquium "Statistische Methoden in der empirischen Forschung"

Sonderprogramm des Sommersemesters 2020: Die Corona Krise – Offene Wissenschaft tut Not

Termin: Dienstag, 7. Juli, 17h per Video-Konferenz

Weiteres Programm und Link über:

https://www.vetmed.fu-berlin.de/einrichtungen/institute/we16/kolloguium

Ongoing Trials During COVID-19: Challenges and Biometric Strategies

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Trial disruption during COVID-19 can take countless forms, from patient retention and missing data challenges, to the need to re-examine endpoint due to new comorbidities or unexpected difficulties with observation. The clinical trial community and regulatory agencies are taking extraordinary measures to mitigate the negative effect the virus has on the conduct of clinical trials. In response to the pandemic, the FDA and EMA are publishing guidance documents on the actions that sponsors of affected clinical trials should take to help ensure the integrity of their studies, and the interpretation of the study results, while safeguarding the safety of trial participants as a first priority. In this presentation we will look at the associated challenges from a biostatistics methodology perspective where especially the estimands concept should provide researchers with a powerful tool to cope with the difficult tasks.