Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 25. Oktober 2022, 17:00 – 18:30 Uhr

Wo: FU Berlin | FB Wirtschaftswissenschaft | Hörsaal 104a | Garystr. 21, 14195 Berlin | U3, Freie Universität (Thielplatz) | S1, Lichterfelde West

Online-Übertragung: der Link wird auf der Website zur Verfügung gestellt

Kai Grosch (Novartis)

How much can dose-exposure-response models improve the developments of drugs? – The limits of model informed drug development

In 2018, the US Food and Drug Administration (FDA) started a pilot program that facilitates the application of model-informed drug development (MIDD) principles. The program suggest the application of pharmaco-statistical models of efficacy and safety from pre-clinical and clinical data to improve drug development knowledge management and decision-making. Since then, Pharmaceutical Industry has participated in this program and recognized benefits generating and applying pharmaco-statistical models in development.

In the current presentation, I will show examples how statistical modeling has been used to inform decision making in human dose finding during drug development and will discuss the benefits and potential risks that are accompanied.