

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 14. November 2023, 17:00 – 18:30 Uhr

Wo: [Campus Charité Mitte | Hörsaal der Nervenlinik | Bonhoefferweg. 3, 10117 Berlin](#)

Online-Übertragung: der Link wird auf der [Website](#) zur Verfügung gestellt

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A Holistic Approach to Improve Chronic Kidney Disease Trials - Unlocking the Potential of Hierarchical Composite Endpoints

Clinical trials in chronic kidney disease (CKD) often utilize composite endpoints comprising clinical events such as onset of end-stage kidney disease (ESKD) and initiation of kidney function replacement therapy (KFRT), along with a sustained large (e.g., $\geq 50\%$) decrease in glomerular filtration rate (GFR). Such events typically occur late in the disease course, resulting in large and long trials in which most participants do not contribute clinical events. More recently, the rate of GFR decline over time (i.e. GFR slope) has been suggested as a more efficient endpoint, which is considered particularly useful in early CKD stages as well as patient populations with slower CKD progression.

This talk will present the use of hierarchical composite endpoints (HCEs) in clinical trials of CKD progression, emphasizing the potential to combine clinical events such as those typically utilized, with the continuous variable of GFR slope, while ranking all components according to clinical significance. Post-hoc analyses of several large CKD trials will illustrate the application of the newly developed kidney HCE including bootstrap-based efficiency comparisons with established endpoints. Furthermore, a novel graphical display will be presented that visualizes overall treatment effects and the contribution of individual components.