

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 13. Januar 2026, 17:00 – 18:30 Uhr

Wo: [Campus Charité Mitte, Raum 02.002, Virchowweg 10, 10117 Berlin](#)

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

Vortragssprache: Englisch

Gernot Wassmer, Friedrich Pahlke, and Daniel Sabanes Bove | RPACT

News and Enhancements of rpact, an R Package for Adaptive Confirmatory Designs

The open-source R package ‘rpact’ is a fully validated, open source, free-of-charge R software package for clinical trial planning, design simulation, and data analysis. It has been under continuous full-time development since 2017, and extensive documentation is provided at www.rpact.org. The package focuses primarily on group sequential and adaptive designs using p-value combination tests, while also supporting fixed-sample designs. It enables users to assess design characteristics of widely used group sequential designs and extends these methods to include interim sample size reassessment based on conditional power. Beyond these approaches, adaptive multi-armed and population enrichment designs that are based on closed combination tests can be assessed by simulation. The application of the designs for simulation, real data, and estimation is possible for continuous, binary, survival, and count data. The capabilities of the software is along the monograph of Wassmer and Brannath, the recently published edition (Wassmer and Brannath, 2025) also contains the relevant rpact software code for reproducing results presented in the book.

We describe new capabilities and enhancements of the software. Most recently, a new function has been added for specifying and transforming futility bounds across various scales, including p-values, effect size, predictive power, and reverse conditional power scale. Its use is demonstrated with practical examples. A second new feature is the ability to define and evaluate designs with delayed responses. The delayed-response group sequential design was originally proposed by Hampson and Jennison (2013), further developments were proposed, e.g., by Schüürhuis et al. (2024). The methodology for multi-stage designs is supported with rpact and can also be extended to the adaptive case. Thirdly, count data designs for the fixed sample and group sequential case can be considered too. As counts and recurrent events are frequently used as primary endpoints in clinical trials, these enhancements substantially broaden the applicability of the package.

Literature

Hampson, L. V., Jennison, C. Group sequential tests for delayed responses (with discussion). *Journal of the Royal Statistical Society: Series B (Statistical Methodology)* 2013, 75, 3–54.

Schüürhuis, S., Konietschke, F., Kunz, C.U. A two-stage group-sequential design for delayed treatment responses with the possibility of Trial restart. *Statistics in Medicine* 2024, 43, 2368–2388.

Wassmer, G., Brannath, W.: *Group Sequential and Confirmatory Adaptive Designs in Clinical Trials*. Springer Science and Business Media, 2016, 2nd edition 2025.