Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 15. Januar 2019, 17:00 – 18:30 Uhr

Wo: Robert Koch-Institut | Nordufer 20 | 13353 Berlin (Wedding),
S41, S42, U9 Westhafen | U9, Bus 142 Amrumer Str

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RPACT R Programming for Adaptive Confirmatory Designs

There is increasing interest by the industry to use R. At the moment, no R package is available for performing confirmatory adaptive designs in a comprehensive sense (e.g., design and analysis for continuous, binary, and survival endpoint). Nevertheless, for group sequential tests there is (for example) the R package gsDesign, developed by Keaven Anderson (copyright Merck Research Laboratories), which is well established and covers many relevant designs. Among the over 13.000 available packages at CRAN (November 2018) there are several packages that address the issue of adaptive designs, most of them with special reference to research results from the authors, but none covers the broad range of applications that is nowadays available. In RPACT (R Package for Adaptive Clinical Trials) particularly, the methods described in the recent monograph of Wassmer and Brannath (Springer, 2016 <doi:10.1007/978-3-319-32562-0>) are implemented and made available for the public.

For design and analysis, the basic features of the current version of RPACT (available on CRAN https://CRAN.R-project.org/package=rpact) include all relevant cases for group sequential designs without sample size re-estimation, adaptive designs that are based on the inverse normal method, and adaptive designs that are based on Fisher's combination test. For analysing the data, besides assessing conditional properties (i.e., conditional power and conditional rejection probability (CRP) under H0) confidence intervals and p-values that account for the adaptive nature of the designs are provided. The validation of the package will be done compliant to FDA/GxP guidelines and to the validation process of “Base R” and “Recommended Packages” as described in: “R: Regulatory Compliance and Validation Issues, A Guidance Document for the Use of R in Regulated Clinical Trial Environments” (The R Foundation for Statistical Computing, December, 2014).