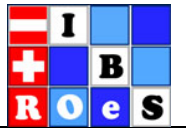
Einladung zum Biometrischen Kolloquium

Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz



SILKE JÖRGENS

ICON Innovation Center, Cologne (Germany)

CONFIRMATORY ADAPTIVE GROUP SEQUENTIAL TRIALS: TREATMENT ARM AND SUBPOPULATION SELECTION BASED ON SURROGATE ENDPOINTS

14. November 2016 um 13:00 Uhr (s.t)

Jugendstilhörsaal, Rektoratsgebäude (BT88)
Medizinische Universität Wien, Spitalgasse 23, 1090 Wien
Plan siehe http://cemsiis.meduniwien.ac.at/allgemeines/anschrift/

Abstract:

Confirmatory adaptive group sequential trials: Treatment arm and subpopulation selection based on surrogate endpoints

Silke Jörgens, ICON Innovation Center, Cologne, Germany

Adaptive group sequential designs which involve multiple test treatment arms or multiple subpopulation of interest often foresee the selection of a subset of these treatment arms or subpopulations at an interim analysis. Using appropriate methods, patients included in these interim analyses can contribute both to the selection decision and to the final confirmatory analysis. Often, this allows a decrease of sample size and study duration. The applicability of such a design, however, depends on suitable operational characteristics of the trial: If the majority of the patients has already been enrolled in the trial, the practical benefit may become very limited. This is especially true for time-to-event data, where the follow-up period may notably exceed the accrual period. In such cases, the use of a surrogate endpoint for the selection decision can enhance the operational characteristics of the trial. Special analysis methods are needed, though, as in the time-to-event case patients may contribute to more than one interim analysis depending on the time point of their enrollment and the observation of their primary event. We present the method implemented in ADDPLAN and give an overview over some properties of this method.