

Einladung zum ZeSOB Kolloquium

Am Montag, **31. Oktober 2016**, um **16:00 c.t.** spricht Herr

Prof. Dr. Arne Ring

(University of the Free State, South Africa & medac, Wedel)

über

Evaluation of medical subgroups in clinical trials

The Draft EMA guideline (on the investigation of subgroups in confirmatory clinical trials) requests sponsors to evaluate the consistency of effects in well-defined subgroups when the clinical trial population was heterogeneous, in order to detect signals of differential treatment effects across the subgroups.

Such evaluations are often based on the application of subgroup-by-treatment interaction tests for assessing consistency. However these interaction tests can only reject, but not confirm “homogeneity”. Another drawback of these tests is that their performance strongly depends on the sample size [Brookes 2001]. With large sample sizes, they might reject homogeneity even when between-group differences are not clinically relevant. Conversely, with small subgroups, even large, clinically important heterogeneity may not be identified.

We propose a new method to for assessing the consistency of treatment effects based on modified criteria which scale the difference of the treatment effect in relation to the overall variability of the treatment effect. Subsequently an equivalence test is proposed and its properties are derived and compared with the interaction test.

For this equivalence test, a “relevance margin” needs to be defined, which might be seen as a drawback of the method. However the interpretation of the results might be practically more appropriate, as differential subgroup effects are assessed for their relevance rather than for significance of the difference.

The presentation will also discuss historical examples of subgroup analyses and outline the current plan for further research.

Der Vortrag findet statt am Montag, 31. Oktober 2016, um 16 Uhr c.t. im Seminarraum des KKS an der Universität Bremen, Linzer Straße 4, 28359 Bremen.

Alle Interessierten sind herzlich willkommen!

(Einladungsvorschlag von Prof. Dr. Werner Brannath)