

# Einladung zum ZeSOB Kolloquium

Am Donnerstag, 6. Dezember 2018, um 16:30 s.t. spricht Herr

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über

## **Two examples of principal stratification estimands and analyses in clinical trials**

Even though causal inference is not explicitly mentioned in the draft ICH E9 addendum on "Statistical Principles for Clinical Trials", it seems to become apparent that the general framework of causal inference is encouraged in this draft guideline. With this in mind we present two case studies on principal stratification estimands and analyses that were recently conducted.

The first example focusses on treatment effect estimation in a subgroup defined by an early on-treatment post-baseline biomarker measurement. This is of clinical interest because in some situations, it is realistic to assume that patients, whose post-baseline biomarker levels indicate that they do not respond to the drug, are also unlikely to respond on clinically relevant outcomes such as time-to event. The second example focusses on treatment effect estimation in the subgroup of patients who would not experience a specific clinical event during the follow-up of the trial (regardless of treatment assignment). This is of clinical interest, because the studied disease is heterogeneous and interest is in the subtype of the disease, where patients do not have this clinical event. Complications in the analysis arise, because the occurrence of the clinical event itself is affected by treatment. In both cases different analyses quite different analysis methods were utilized, which are outlined during the presentation.

**Der Vortrag findet statt am Donnerstag, 6. Dezember 2018, um 16:30 Uhr s.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)