

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 03. November 2015, 17:00 – 18:30 Uhr

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

Peter Jakobs (PAREXEL International, Berlin, Germany)

Analysis of Recurrent Adverse Events of Special Interest: an Application for Hazard-Based Models

For decades, safety risks on study or product level have been summarized by incidence estimates: typically, with N_j denoting the number of subjects who received at least one dose of study treatment j and $n_{j,x}$ denoting the number of subjects in treatment group j who experienced at least once an adverse event x (e.g., categorized as MedDRA Preferred Term), such an incidence is estimated by $n_{j,x} / N_j$ times 100%. Treatment groups have been compared by related estimates like risk difference, risk ratio -and odds ratio.

Timing, duration, recurrence as well as duration of adverse events has been ignored frequently.

A trend for utilizing time-to-first-event methodology (like cumulative incidence estimates and Cox proportional hazard regression models) in safety assessments has been observed over the last years, but this approach is still limited.

The presentation will outline some statistical methodology for evaluating risks for recurrent (or otherwise complex) safety events of special interest, focusing on hazard-based models for counting processes and multi-state models. For example, states in a multi-state model for adverse events of special interest may be defined

- by a small set of adverse events that increase the risk for a serious adverse event
- by administration of certain concomitant medication(s) over the course of the study (that either change the risk for such adverse events or are used to treat such adverse events).

A fictitious case study analysis will be presented as well.