

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 14. November 2017, 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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Basket trial designs – inside and outside oncology

The focus of modern medicine has shifted from broad spectrum treatments to targeted therapeutics leading to new challenges for the design and analysis of clinical trials. One such new class of designs has been termed “basket trials”.

In oncology, a basket trial is a trial that enrolls patients with tumours of a variety of different histologies but the same common set of driver mutations. That is, within this approach patients are enrolled based upon having a specific mutation that is targeted by the compound.

Various designs have been proposed for basket trials within oncology which can reduce the sample size and the duration of the trial and increase the power as compared to implementing independent parallel designs in each basket.

While basket designs are now commonly used in oncology, these designs are barely used outside oncology. However, interest in the design of basket trials is increasing in other therapeutic areas. The main problem is that most statistical methods used for basket trials in oncology cannot easily be adapted to other therapeutic areas. In oncology in each basket, all patients are treated with the new compound, i.e. each basket has only one study arm. While single-arm trials are still accepted by regulatory authorities for oncology trials, this is not necessarily the case for other therapeutic areas.

In this talk, I will give a brief overview over basket trial designs used in oncology. Focusing on designs that allow pooling of data from different baskets after an interim analysis, I will discuss different possibilities to extend these designs to other therapeutic areas allowing for a control arm within each basket.