

Speakers: Haiyan Zheng (University of Bath)

Date: 12/12/2023 at 13:15 in 1 West 2.03

Title: Statistical design and analysis of clinical trials with multiple strata

Abstract:

The paradigm of drug development has been revolutionised due to advances in genomic technology. Patients can now be stratified into small subgroups that may receive different benefits from a new treatment. This has brought a paradigm shift from one-size-fits-all approach towards precision medicine to deliver the right treatment to the right patients at the right time. One innovative approach to precision medicine is to conduct basket trials that simultaneously evaluate a new treatment in patients of various cancer types under an overarching protocol. Eligible patients nonetheless share a common feature (e.g., a genetic aberration, or mechanism of drug action), on which the new treatment may potentially improve patient outcomes. Sophisticated analysis models for basket trials feature borrowing of information between subgroups (strata). They are preferred over the stand-alone analyses which regard the strata in isolation, since a joint analysis can generally yield higher power to detect a treatment benefit while accommodate patient's heterogeneity.

In this talk, I will introduce a few representative examples of basket trials, together with a new Bayesian model that characterise the complex data structure. More specifically, this model reflects the concern that the treatment effect in some strata may be more commensurate between themselves than with others. Closed-form sample size formulae can be derived to enable borrowing of information between commensurate strata. Perspectives will be also given on the future methodology development for basket trial designs.