

Group sequential and adaptive designs for clinical trials.

Course No.: 2007-Nyhed-3

Purpose and contents: It has become standard practice to incorporate formal data monitoring procedures into the design and conduct of long-term clinical trials – especially so with the increasing use of Data Monitoring Committees (e.g. FDA Guidances E6, E9). A unified formulation allows easy implementation with many types of design and a great variety of endpoints. We will survey the main ideas of group sequential procedures. The course will cover: one-sided, two-sided and equivalence designs; normal, binary, survival, regression, and longitudinal endpoints; estimation; error spending, nuisance parameters, stochastic curtailment.

More recently, methods have been proposed whereby the design of a trial can be modified in mid-course without affecting the Type I error. This may be in response to external factors, or it could be a reaction to unblinded data observed in the study itself. Such modifications may include increasing the sample size to increase the statistical power, changing the study population, modifying the treatment, changing the goal from superiority to non-inferiority or vice versa, or reducing the number of treatment arms. Some methods require these “adaptations” to be rigid, with rules pre-specified in the protocol; others may be flexible, permitting unplanned changes at unplanned interim analyses. We will describe these procedures in detail and discuss the benefits and drawbacks of using the adaptive approach.

Throughout, statistical software (EaSt) will be used for illustrative examples.

Participants: Ph.D.-students and other interested scientists. Max. 40 participants.

Form: 2 full days of lectures.

Language: English

Course material: Group Sequential Methods with Applications to Clinical Trials, by C. Jennison and B.W. Turnbull. Chapman & Hall.

ECTS-points: 2.

Course director: Professor Niels Keiding.

Teachers: Chris Jennison (University of Bath, UK), Bruce Turnbull (Cornell University, USA)

Time: 7-8 May 2007 from 9-17.

Place: Kommunehospitallet.

Total Course Fee: DKK 1,900 of which the operating costs amount to DKK 300.

Course secretary: Susanne Kragtkov Laupstad, Department of Biostatistics, University of Copenhagen. Tel. 35 32 79 01.

Registration: Before 1 April 2007. No admission after deadline. Admission for PhD students will be allocated on a first-come, first-served basis. Applications from external participants will be considered after the closing date. The application must be sent to: PhD Administration, Blegdamsvej 3B, DK-2200 Copenhagen N.