Summer school
Group sequential and adaptive clinical trial designs
17-19 October, 2019 – PfalzAkademie, Lambrecht

German Region of the
International Biometric Society
(IBS-DR)

Course content

Group sequential and adaptive methods are commonly used in clinical research and pharmaceutical development to reduce the expected duration or to increase the flexibility of confirmatory clinical trials. Such trials can be modified or stopped prematurely at one or more planned interim analyes. Specialized statistical methodology allow to maintain trial integrity and validity, e.g. control of the type I error rate, despite these interim analyses and design modifications.

This summer school provides an introduction to group sequential and adaptice designs, and also covers advanced topics. The theory will be illustrated with case studies from the pharmaceutical industry.

Each module of this course includes a computer practical. We will use the R software package rpact (R Package for Adaptive Clinical Trials, https://www.rpact.com/), a validated, comprehensive and freely available package for the design, simulation and analysis of group sequential and adaptive trials.

Target audience

The target audience of this summer school are (bio-)statisticians interested in flexible clinical trial designs. Basic knowledge of statistics and clinical trials is expected. Participants should bring their personal laptop, with the statistics software R already installed. Basic knowldedge of R is expected. Prior knowledge of flexible designs or of the R package rpact are not expected.

Recommended reading

Gernot Wassmer and Werner Brannath (2016): Group Sequential and Confirmatory Adaptive Designs in Clinical Trials, Springer.

Schedule

Day 1 14:30-18:00	Group sequential designs – Introduction • Pocock and O'Brien-Fleming designs for normally distributed data • Non-normally distributed data, flexible timing of interim analyses, stopping for futility • Clinical case study with a time-to-event endpoint • Introduction to the R package rpact
Day 2 9:00-12:30	Adaptive designs – Introduction • p-value combinations and conditional error functions • Early stopping and sample size recalculation
Day 2 14:00-17:30	Group sequential designs – Advanced topics • Multiple endpoints, hierarchical testing of endpoints • Inference after early stopping
Day 3 9:00-12:30	Adaptive designs – Advanced topics • Inference after an adaptive design • Studies with multiple objectives (multiple active treatment arms, multiple populations („enrichment designs“))

Faculty

Gernot Wassmer
University Köln

Marcel Wolbers
Roche

Kaspar Rufibach
Roche

Marc Vandemeulebroecke, Novartis

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Location
PfalzAkademie, Franz-Hartmann-Str. 9, D-67466 Lambrecht
www.pfalzakademie.de

Foto: Manfred Czerwinski

Course fees
Members of the German Region of the IBS (IBS-DR):
Students / Academic / Industry:
125€ / 250€ / 350€

Others (not IBS-DR members):
Students / Academic / Industry:
250€ / 375€ / 475€

Membership in the German Region of the IBS (IBS-DR) is free of charge for students.

Accommodation and catering
Accommodation and meals (breakfast, lunch, dinner) are on site and included in the course fees.

Dates
17-19 October 2019
Arrival: Thursday, 17.10.2019, before 14:00
Departure: Saturday, 19.10.2019, from approximately 13:00

Registration
Please register through this link:
https://form.jotform.com/90451347804153

For questions about the content of this course:
Marcel Wolbers
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For organisational questions:
Lukas Pfaff
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Definitive registration and payment until 15.6.2019
Please register by 15.6.2019. For cancellations after this date, 50% of the registration fees will be charged. The entire fees are due in case of a late cancellation after 30.8.2019. We reserve the right to cancel this event for important reasons, e.g. in case of too few registrations. In this case, already paid course fees would be reimbursed, but travel expenses or other costs cannot be reimbursed.

Course language
If all participants are German speakers, the course will be done in German. Otherwise the course language will be English. The course material is in English.

Number of participants
The number of participants is restricted to be not greater than 36.