Basel Biometrics Society full-day training course
Basel, 13th September 2022

Full-day course on advanced group-sequential and adaptive confirmatory clinical trial designs, with R practicals using rpact

Date and Time: 13th September 2022, 9:00-17:30
Venue: 4th floor, Roche Building Hochstrasse 16, Basel
(neighbouring SBB railway station)

The Basel Biometrics Society (BBS) offers a course on advanced topics in group-sequential and adaptive clinical trial designs. The course is intended for biostatisticians from pharma and academia who are interested in learning more about such designs. Topics covered are the efficient use of interim analyses, an introduction to adaptive trials and sample size recalculation, the use of closed testing procedures for adaptive trials with multiple objectives, and multi-arm multi-stage designs. Examples from real clinical trials will be used throughout the presentations. We also aim to discuss operational aspects of implementing such designs in practice. Finally, a member of the ICH E20 working group (Uli Burger and/or Frank Bretz) will report on his experience and insights about using these designs in drug development, also in connection with the ongoing work on a new ICH guideline, E20, on adaptive designs.

The course will be a mix of presentations and practicals with R using rpact. We will assume basic familiarity with group-sequential designs and R. Participants are asked to bring a laptop with R and rpact (version 3.2.3 or higher) installed. It is the ambition of the instructors to make this course very interactive.

Instructors: Kaspar Rufibach (Roche), Marc Vandemeulebroecke (Novartis), Gernot Wassmer (rpact), Marcel Wolbers (Roche).

For industry participants, a fee of Sfr 70 per participant will be charged via company-wise block bookings. Participants from other institutions (academia, collaborative groups) are asked to pay Sfr 70 in cash when registering at the beginning of the event in exchange for a certificate of attendance. Registration entails attending the course and lunch on site. For organizational reasons, the number of participants is limited, on a first come first served basis. Please register no later than 31 August 2022 under this link. Since seats are limited and for catering purposes, we also ask you to cancel your participation as early as possible by sending an email to kaspar.rufibach@roche.com in case you have registered and cannot attend, so that we can give others a chance to attend.

We will organize a formal dinner on the evening of the 12th September in a Restaurant in Basel. On 14th & 15th September the 7th EFSPI regulatory statistics workshop will take place in Basel as well. We invite all participants to consider attendance at both events. A first announcement for the EFSPI workshop will be shared soon.

Program:

09:00 – 09:10	Welcome
09:10 – 10:00	Theory: Efficient use of interim analyses (Marcel or Kaspar)
10:00 – 10:40	Theory: Introduction adaptive trials & sample size re-calculation (Marc)
10:40 – 11:00	Coffee break
11:00 – 12:30	Practical: Introduction to rpact (Gernot), exercises (all)
12:30 – 14:00	Lunch
14:00 – 14:30	Theory: Closed testing principle in adaptive trials (Gernot)
14:30 – 15:30	Multi-arm multi-stage designs (Kaspar or Marcel)

15:30 – 16:00 Coffee break

16:00 – 17:00 Practical: Exercises (all)

17:00 – 17:30 Considerations when using adaptive designs in drug development (Uli Burger, Roche)

17:30 – 18:00 General Q&A (all)

Bios of instructors

Kaspar Rufibach joined Roche in 2012. In his first role, he was the responsible statistician for a global filing of a large oncology study. In 2015 he moved on to the Methods, Collaboration, and Outreach group within Roche Biostatistics. As a member of that group, he provides consulting to Roche statisticians, gives trainings on all levels in- and externally, mentors students, and interacts with external partners across industry and the academic community. His current topics of research interest are methods to optimize study designs, quantification of the probability of success of clinical trials, estimands, advanced survival analysis, and in general nonparametric statistics. Before joining Roche, Kaspar received training and worked as a statistician at the Universities of Bern, Stanford, and Zurich. Find more about Kaspar's work on http://www.kasparrufibach.ch.

Gernot Wassmer is adjunct Professor for Biostatistics at the Institute of Medical Statistics, University of Cologne, Germany. He received his PhD 1993 at the University of Munich, Germany, and was a Research Fellow at the Institute of Statistics, University of Munich, at the Institute for Epidemiology, GSF Neuherberg, and at the Institute of Medical Statistics, University of Cologne. In 2017, he was a guest professor at the Medical University of Vienna, Austria. His major research interest is in the field of statistical procedures for group sequential and adaptive plans in clinical trials. Starting in 2018, together with Friedrich Pahlke, he has been developing the rpact package. He has been a member in independent data monitoring committees for international, multi-center trials on different therapeutic fields and also serves as a consultant for the pharmaceutical industry.

Marc Vandemeulebroecke joined Novartis in 2006, coming from Schering AG in Berlin. He has been supporting development programs in early and late phase development across various disease areas (incl. Neuroscience, Gastrointestinal, Parasitology, Cardio-metabolic, Immunology, Transplant and Hepatology) as statistician and pharmacometrician. Currently he is Global Group Head for Dermatology. Marc holds a maîtrise in mathematics from the University Paris XI, a diploma in mathematics from the University of Münster, a PhD in mathematical statistics from the University of Magdeburg, and an MSc in PKPD modeling from the University of Manchester. He received the Gustav-Adolf-Lienert award from the German Region of the International Biometric Society (IBS) for his PhD thesis, which focused on adaptive designs. He co-authored various scientific publications and one R package. Marc's current interests include effective quantitative graphics and statistical learning.

Marcel Wolbers is a member of the Methods, Collaboration, and Outreach (MCO) group within Roche Biostatistics. He provides consulting to statisticians and broader project teams, teaches internally and externally, is a member of multiple academic and industry working groups, conducts research, and mentors statisticians and interns. Marcel also serves on the board the Basel Biometric Society (BBS) and as an associate editor for Pharmaceutical Statistics and the Biometrical Journal. His research interests include innovative designs, estimands for longitudinal data, prognostic models, subgroup analyses, competing risks, and causal inference. After completing his PhD in mathematical statistics at ETH Zürich, Marcel worked as a study statistician at Roche from 2003-2005 and re-joined Roche as a member of the MCO in 2016. In between, he was a senior biostatistician at CEB Basel and spent 7.5 years as the head of biostatistics at the Oxford University Clinical Research Vietnam based in Ho Chi Minh City.

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