



## Basel Biometrics Society full-day course Basel, 1<sup>st</sup> March 2018

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

**Date and Time:** 1st March 2018, 8:20-17.00  
**Venue:** Roche Building 683 Viaduktstrasse, Auditorium

The BBS would like to offer an introductory course on group-sequential and adaptive clinical trial designs. The course is intended for biostatisticians who are interested in learning more about or are exposed to such designs, whether in pharma or academia. Topics covered are basic concepts of group-sequential and adaptive designs for confirmatory clinical trials, flexible timing of interim analyses, futility analyses, possible modifications at an interim analysis, implications for inference if trials are modified or stopped at an interim analysis, and testing of secondary endpoints. Examples from real clinical trials will be used, including discussions of Health Authority interactions on specific aspects of such flexible designs. We also aim to discuss operational aspects of implementing such designs in practice and available regulatory guidelines. The course will be a mix of presentations and practicals with R. Participants are asked to bring a laptop with R installed (details on R packages required will be shared with registered participants via e-mail before the course). Overall, it is the ambition of the instructors to make this course very interactive.

Instructors: Kaspar Rufibach (Roche), Daniel Sabanés Bové (Roche), Marc Vandemeulebroecke (Novartis), 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 20 in cash when registering at the beginning of the event. For organizational reasons, the number of participants is limited, on a first come first served basis. Please register no later than 16th February by sending an e-mail to Laurence Guillier ([laurence.guillier@roche.com](mailto:laurence.guillier@roche.com)) or Barbora Martinec ([barbora.martinec@roche.com](mailto:barbora.martinec@roche.com)). Since seats are limited and for catering purposes, we also ask you to cancel your participation as early as possible in case you have registered and cannot attend, so that we can give others a chance to attend.

#### Program:

08:20	Welcome
08:30 – 10:00	Basics of group-sequential clinical trial designs (KR, MW)
10:00 – 10:30	Coffee break
10:30 – 11:00	Inference for group-sequential designs: bias of effect estimates, 2 <sup>nd</sup> endpoints (KR, MV)
11:00 – 12:00	Practicals (DS)
12:00 – 13:00	Lunch
13:00 – 14:30	Basics of adaptive clinical trial designs (MV)
14:30 – 15:00	Inference for adaptive designs (MV)
15:00 – 15:30	Coffee break
15:30 – 16:30	Practicals (DS)
16:30 – 17:00	Q & A, discussion
17:00	Closure of event

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We look forward to your participation! Kind Regards,

Kaspar Rufibach, Daniel Sabanés Bové, Marc Vandemeulebroecke, Marcel Wolbers (on behalf of the BBS)

### 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. Kaspar's methodological and collaborative research so far led to more than 80 co-authored scientific publications, 11 R-packages on CRAN, as well as an introductory statistics text book in German (Pearson, 2013). Before joining Roche, Kaspar received training and worked as a statistician at the Universities of Bern, Stanford, and Zurich.

**Daniel Sabanés Bové** joined Roche in October 2013, and has supported multiple early phase Oncology projects from the Basel headquarters, which included global health authority interactions. Before that, he received a Master of Science in Statistics from the Ludwig-Maximilians-Universität München in 2009 and a PhD in Statistics from the University of Zurich in 2013. Daniel received the Bernd-Streitberg young researcher award from the German Region of the International Biometrical Society, and co-authored the book "Applied Statistical Inference" (Springer, 2014). He developed the R-package "crmPack" for model-based dose escalation designs and gave Roche-internal and also external (ICTMC 2017) tutorials on this topic. Other current interests comprise endpoints in cancer immunotherapy and associated decision making, as well as reproducible reporting of standard designs and analyses.

**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 item response theory and statistical learning.

**Marcel Wolbers** completed his PhD in mathematical statistics at ETH Zurich in 2002. After his PhD, he worked for Roche, the Basel Institute for Clinical Epidemiology and Biostatistics, and the University of Oxford. At the University of Oxford, he was the head of Biostatistics at the Oxford University Clinical Research Unit Vietnam and based in Ho Chi Minh City, Vietnam, for more than 7 years. Marcel re-joined Roche in 2016 where he was the responsible statistician for the US filing of a large oncology trial and is a full member of the Methods, Collaboration, and Outreach group within Roche Biostatistics. His current research interests include flexible designs, subgroup analyses, longitudinal data, and competing risks. Marcel has co-authored more than 100 scientific publications, many of them in leading medical and statistical journals.

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Location: Roche Bau 683 Viaduktstrasse

### *Mit öffentlichem Verkehr* *Via local public transport*

**Bus 31** ab Hoffmann-La Roche  
oder **Bus 31/34** ab  
Rosengartenweg bis Wettsteinplatz  
**Tram 2** bis Markthalle

Bus 31 from the Hoffmann-La  
Roche stop or Bus 31/34 from  
the Rosengartenweg stop to  
Wettsteinplatz  
Tram 2 from Wettsteinplatz to the  
Markthalle stop

### *Zu Fuss* *On foot*

#### **Ab Bahnhof SBB**

← Aus dem Haupteingang  
links in die Centralbahnstrasse  
↑ Geradeaus über die Kreuzung  
in die Viaduktstrasse,  
Haupteingang: Viaduktstrasse 33

#### **From SBB station**

← After leaving the station through  
the main exit, turn left onto  
Centralbahnstrasse and walk  
straight ahead to the next inter-  
section  
↑ Go straight across the intersec-  
tion onto Viaduktstrasse  
Main entrance:  
Viaduktstrasse 333

