



## **ISCB Short Course in Budapest**

27-28 November 2014

**Course title: Novel approaches to multiple test problems, with applications to adaptive designs and dose finding**

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### **Abstract**

The issue of multiplicity often arises in the design and analysis of clinical trials. Common multiple test problems include comparing several doses with a control, assessing the benefit of a new treatment for more than one endpoint, combined non-inferiority and superiority testing, or any combination thereof. One particular application arises in confirmatory adaptive design trials, when multiplicity adjustments must be made to account for adaptations made during the study. Another application arises in dose finding studies, where multiplicity due to model uncertainty has to be addressed. This 1.5-day course will begin with the introduction of the basic fundamentals of multiplicity methodology, and continue through novel methods and strategies for addressing multiplicity concerns. These techniques will be demonstrated with several case studies.

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### **About the authors:**

Frank Bretz joined Novartis in 2004, where he is currently Global Head of the Statistical Methodology group. He has supported the methodological development in various areas of drug development, including dose-finding, multiple comparisons, and adaptive designs. He is an Adjunct Professor at the Hannover Medical School and the Shanghai University of Finance and Economics.

Franz König is currently Associate Professor at the Section of Medical Statistics at the Medical University of Vienna, Austria. From 2008 till 2010 he was seconded to the European Medicines Agency (London, UK) as statistical expert in the Unit Human Medicines Development and Evaluation. He has served as Guest Editor for Special Issues in Biometrical Journal and Statistics in Medicine. He is currently the work package leader on “adaptive designs” in the EU Fp7- funded research project IDEAL.

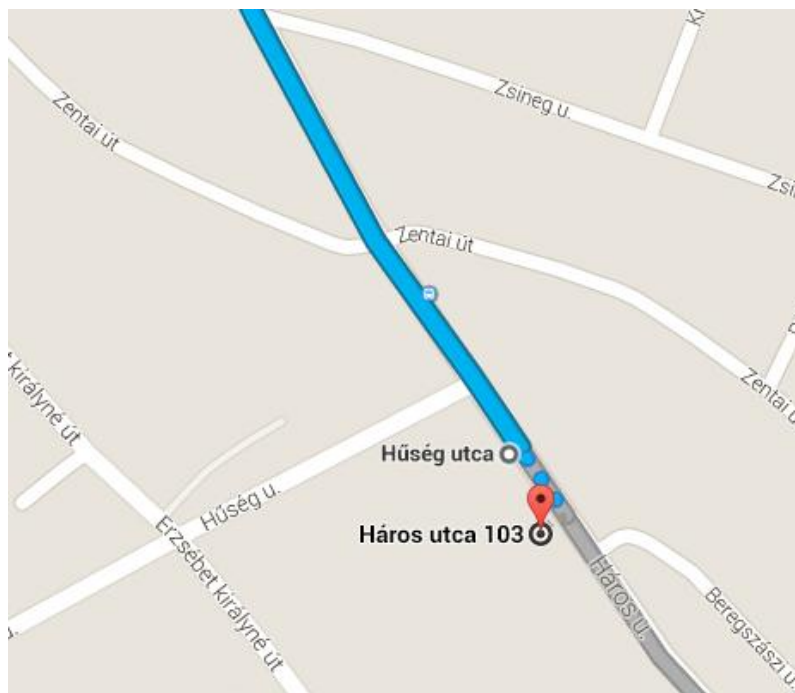


### **Registration fees:**

For attendants from ISCB target countries: 60 Euros

For attendants from other countries: 180 Euros

**Location:** Accelsiors CRO and Consultancy Services, Háros Street 103, Budapest 1222



Recommended route: Underground M4 to Kelenföld Railway station, then Bus 141 to Hűség utca.

### **Hotels in the neighbourhood:**

Hotel Menthol

Belle Fleur Pension

Hotel Rubin