

# First Announcement

## BBS Fall Conference 2010 Monday, October 04, 2010

*Emerging Topics in Pharmaceutical Statistics:  
Adaptive Designs and Non-inferiority*

Monday, October 04, 2010 from 9:00-17:00  
at the Hotel Bildungszentrum 21,  
Missionstrasse 21, 4003 Basel

**Cost: A nominal fee to cover basic costs will be collected at registration prior to the conference:**

CHF 50 for industry  
CHF 20 for academia  
Students free

**09:00 – 9:15 Welcome and Announcements**  
Michael Branson (Novartis)

**9:15 – 12:15 Morning session**

**Emerging Topics in Adaptive Designs**  
Frank Bretz (Novartis)

09:15 – 09:45 Helmut Schäfer (University of Marburg)  
*Optimized and flexible designs for genome-wide associations studies*

09:45 – 10:15 Maximo Carreras (Roche)  
Point Estimation in Two-Stage Adaptive Designs With Mid-Trial Treatment Selection

10:15 – 10:45 David Lawrence (Novartis)  
*The A to Z of DMC interaction in a phase II/III adaptive design with treatment selection*

10:45 – 11:15 Reinhard Eisebitt (ClinResearch)  
Methods to protect the blinding, including controlled emergency unblinding, in adaptive design trials with flexible randomization schemes

11:15 – 11:45 Tim Friede (University of Göttingen)  
*The role of DMCs in adaptive design trials: The perspective of a DMC member*

11:45 – 12:15 Sue-Jane Wang (FDA)  
*Adaptive Design Consideration: A Regulatory Perspective on How to Maintain Validity and Integrity of Trials*



**12:15 – 13:30 Lunch break**

**13:30 – 16:30 Afternoon session**

**Emerging Topics in Non-inferiority**

Fred Sorenson (Quintiles Consulting)

13:30 – 14:30 James Hung (FDA)

*Emerging Challenges in Design and Analysis of Non-inferiority Trials*

14:30 – 15:00 Franz König (EMA)

15:00 – 15:30 Ralf Bender (IQWiG)

*The importance of Non-inferiority testing in benefit assessments of medical interventions*

15:30 – 16:00 Heinz Schmidli (Novartis)

Estimating the placebo-effect in a non-inferiority trial: a case study

16:00 – 16:30 Industry representative to discuss non-inferiority & HTA - TBD

**16:30 Concluding remarks**

Uli Burger (Roche)