

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)