

Please take note of the following in your agendas

BBS
Basler Biometric Section

BBS Seminar to be held on May 10, 2011:

*Comparative Quantitative Assessments:
Benefit-Risk & Effectiveness*

Date/time & Location:

Tuesday, May 10, 2011 from 09:00-17:00
Biozentrum der Universität Basel
Klingelbergstrasse 70
4056 Basel

AGENDA

- 9:00-9:10 WELCOME AND ANNOUNCEMENTS**
Michael Branson, Novartis, Switzerland
- 9:10-12:45 SESSION I: COMPARATIVE EFFECTIVENESS**
Chair: Fred Sorenson, Quintiles, Switzerland
- 9:10 **Chrissie Fletcher** (Director and Head of International Biostatistics, Amgen, UK):
Industry Perspective on Comparative Effectiveness Research (CER) and the impact of Health Technology Assessment (HTA) in Europe
- 9:50 **Melvin “Skip” Olson** (Executive Director HE&OR, Novartis, Switzerland):
Some Issues with Indirect Comparisons
- 10:30-10:45 Coffee break
- 10:45 **Friedhelm Leverkus** (Director Health Economics and Outcomes Research, Pfizer, Germany):
Health Care Reform in Germany and Update on IQWiG Requirements
- 11:25 **Marlene Gyldmark** (Head of Modelling, Outcomes Research, Statistics and Epidemiology, Roche, Switzerland):
Some issues with Health Economic Modeling
- 12:05 **John Doyle** (VP Market Access, Quintiles Consulting, USA):
Effect of Comparative Effectiveness Research on Drug Development Innovation: a 360° Appraisal and Summary Discussion
- 12:30-13:30 LUNCH BREAK**



BBS Seminar

Comparative Quantitative Assessments: Benefit-Risk & Effectiveness

13:30-16:55 **SESSION II: BENEFIT-RISK**

Chair: Jürgen Kübler, Novartis, Switzerland

13:30 **Deborah Ashby** (Professor Medical Statistics, University of London, Bart's and the London Queen Mary's, School of Medicine and Dentistry, UK) :
Current Methodological Approaches to Benefit-Risk Decision-Making

14:10 **John Ferguson** (Global Head, Pharmacovigilance & Medical Safety, Novartis Vaccines and Diagnostics, USA):
*Structured Benefit-Risk Optimization (BRO):
State-of-the-art and Role of Fully Quantitative Decision Support Tools*

14:50-15:05 Coffee break

15:05 **Michael Forstner** (Integrated Safety Risk Manager, Roche, Switzerland):
Considerations for Implementing a Quantitative Benefit-Risk Assessment

15:45 **Richard Nixon** (Statistician, Modeling & Simulation, Novartis Pharma):
Benefit-Risk Assessment of Multiple Sclerosis Treatments: Lessons Learnt in the use of Multi-Criteria Decision Analysis

16:25 **John Doyle** (VP, Quintiles Consulting & Columbia Univ. NYC, USA):
Convergence of CER and BRA and Concluding Summary Discussion

16:55 **CONCLUDING REMARKS**
Uli Burger, Roche, Switzerland

17:00 **END OF MEETING & ADJOURN**