

**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**

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**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**