

Please take note of the following in your agendas

## BBS Seminar to be held on September 25, 2012:

*Benefit-Risk & Comparative Effectiveness*

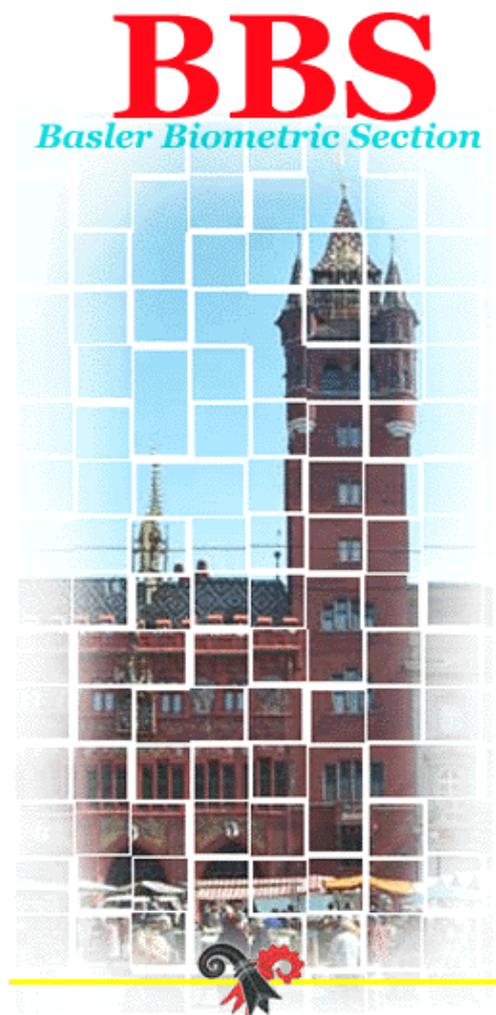
### Date/time & Location:

Tuesday, September 25, 2012 from 08:45-16:15  
Hörsaal 6, Markgräflerhof, Zwischengeschoß,  
Universitätsspital Basel  
Hebelstr. 10  
4031 Basel

This Seminar is free and there is no need to register in advance.

### AGENDA

- 8:45 – 9:00**      **WELCOME AND ANNOUNCEMENTS**  
Michael Branson, BBS President (Novartis)
- 9:00 – 12:45**    **SESSION I: BENEFIT RISK**  
Chair: Conny Berlin (Novartis)
- 9:10                **Filip Mussen** (Janssen)  
The use of frameworks and quantitative methods for regulatory benefit-risk decision making: a status update.
- 9:40                **Andrea Beyer** (University Groningen)  
Understanding the risk tolerance of regulatory assessors in Europe:  
The role of quantitative models in risk communication.
- 10:10 – 10:30    Discussion
- 10:30 – 10:45    Coffee break
- 10:45                **Christoph Dierig** (Bayer)  
A Case Study using the BRAT framework for Benefit Risk Assessment: A Generalization of the NNT/NNH concept.
- 11:15                **Richard Nixon** (Novartis)  
A Case Study using the BRAT framework for Benefit Risk Assessment:  
Application and visualization of Multi-Criteria Decision Analysis (MCDA).
- 11:45 – 12:05    Discussion



## **BBS Seminar**

### **Benefit Risk & Comparative Effectiveness**

---

- 12:05            **Christian Hove Rasmussen** (Novo Nordisk)  
Benefit-Risk Assessment from a Clinical Point of View: a structured approach with focus on transparency, clinical significance and visualization.
- 12:35 – 12:45    Discussion
- 12:45 – 13:45    LUNCH BREAK**
- 13:45 – 16:00    SESSION II: COMPARATIVE EFFECTIVENESS**  
Chair: Fred Sorenson (BBS Treasurer)
- 13:45 – 14:25    **Fred Sorenson** (BBS)  
Benefit-risk assessment and Comparative Effectiveness Research: Are they really converging?
- 14:25 – 15:05    **Ralf Bender** (Head of Medical Biometry, IQWiG, Germany)  
Biometrical requirements in (early) benefit assessments
- 15:05 – 15:45    TBC (NICE representative, United Kingdom)  
Key elements contained in the upcoming 'Guide to Methods of Technology Appraisal' recently released from NICE for review
- 15:45 – 16:00    Discussion
- 16:00            CONCLUDING REMARKS**  
(Conny Berlin and Fred Sorenson)
- 16:15            END OF MEETING & ADJOURN**  
Uli Burger (Roche)