



EFSPI and BBS European Statistical Meeting on Oncology June 24th, 2010 - Basel



On June 24th the Basel Biometrics Society (BBS) and the EFSPI organized this one day meeting in Basel with more than 80 attendees. After an introduction by Hans-Ulrich Berger (Hoffmann-La Roche) there were contributions by seven experts in the field from various countries with different backgrounds.

Bertil Jonsson (Medical Products Agency) gave a very interactive presentation sharing his thoughts around methodological issues including Progression Free Survival, Independent Review versus Investigator Assessment, and the role of interim analyses.

Claire Watkins (AstraZeneca) presented the real life IRESSA story describing the meandering path to registration in a biomarker targeted subpopulation in patients with NSCLC. She also presented lessons learned like the impact of the co-development of a diagnostic tool.

Stuart Bailey (Novartis) presented the Bayesian dose finding methods (replacing the conventional 3+3 designs) which are now standard practice in his company. He also described the interactions with review boards and regulators to explain this novel methodology.

Jonas Wiedemann (Hoffman-La Roche) explained an intra-patient dose escalation case study that has just started. Like the previous speakers he highlighted the importance of open minded clinicians.

Simon Wandel (Novartis) discussed the problem to assess the clinical response in subpopulations. He proposed a Bayesian hierarchical modeling approach that incorporated the potential heterogeneity across the subpopulations.

Marc Buyse (IDDI and University of Hasselt) described various applications of the Time to Progression (TTP) Ratio (i.e. TTP second line treatment / TTP first line treatment), including the open ends / limitations of this approach. He provided a clear message about the importance of randomization in personalized medicine. Cong Chen (Merck) gave his presentation via webcast which went very well thanks to the excellent facilities of the venue. He described the role of optimal cost effective go-no go decisions replacing the traditional qualitative decision making process. This resulted in a change of strategy in his company for POC trials in oncology (smaller and more trials).

A panel discussion completed this meeting.

The beautiful weather in Basel, the excellent organization of this meeting together with the lively presentations made it a very successful day.

Pierre Verweij and Egbert Biesheuvel