**European Statistical Meeting on Modelling and Simulation with applications to longitudinal data**

On September 13th 2012 EFSPI organized a one day meeting on Modelling and Simulation, together with the Basler Biometric Society (BBS) and Modelling & Simulation Basel (MSB). Over 80 attendees with various backgrounds attended this meeting.

After the opening by François Aubin (EFSPI) and Nicolas Frey (MSB), Stephen Senn (CRP-Santé) gave the first presentation of the day. He noticed the increased enthusiasm for modelling in the pharmaceutical industry, but stressed that simple things which could bring even bigger dividend are often overlooked.
Norbert Benda (BfArm) presented a regulatory view on the use of modelling and simulation. He acknowledged the role of M&S in internal decision making and dose selection, but indicated that independent confirmation would still be required in Phase III. M&S could have a high regulatory impact in small populations.

Chris Campbell (Mango Solutions) mentioned a number of good practices which included communication with other quantitative scientists. He also gave an overview of the R-based MSToolkit to simulate clinical trials and evaluate designs.
Carl-Fredrik Burman (AstraZeneca), who gave his presentation via telephone reflected on the role of modelling and simulation in the pharmaceutical industry by going through seven theses. He also called for statisticians to adopt a more flexible mindset and be willing to embrace new, useful methodology.

Ulrich Beyer (Roche) gave an overview of how statisticians in his company approach longitudinal analysis using methods ranging from Last Observation Carried forward to Non-Linear Mixed Effects Models.
Benjamin Ribba (INRIA) presented a model to predict long-term clinical outcome from early clinical evaluation in patients with low-grade glioma (a progressive brain tumor). lThe model led to the proposal of an optimised therapeutic regimen, likely to improve the outcome.

Didier Renard (Novartis) addressed the question whether the size of a Phase III study could be reduced by optimizing analysis methodology for longitudinal data. By averaging over pre-specifying Markov models efficiency was increased and the sample size could be lowered accordingly. He also shared the regulatory feedback on the approach.
Cheikh Diack (Roche) presented a model to predict survival in a phase III trial based on longitudinal tumor response in phase II trial in patients with colorectal cancer.

A lively panel discussion closed the meeting.

Pierre Verweij and François Aubin