Benefit-Risk Assessment Methodology Workshop

Statistical Issues in Medical Statistics, FMS/DSBS 5th Joint Workshop

7 June 2012, University Hospital, Malmö, Sweden, (Copenhagen area)

An increase in the use of quantitative Benefit-Risk Assessment methods has been proposed to aid in the evaluation of new medicinal products by regulatory bodies and reimbursement committees throughout the world. This workshop will provide a forum to hear about the latest developments in the applications of these methods from a world-leader in this area – keynote speaker Larry Phillips -- from representatives of European regulatory bodies, and from practioners in the pharmaceutical industry and academia. The workshop includes presentations from each of these perspectives, as well as an opportunity to interact with the speakers in a panel discussion.

AGENDA

09.15-10.00	Registration, Coffee/Tea, Breakfast
10:00	**INTRODUCTION** from Keynote Speaker **Benefit-Risk Modelling of Pharmaceuticals: Where are we now?** Professor Lawrence Phillips – London School of Economics
10:30	**Quantitative Methods Across the Product Lifecycle - a Personal Perspective** Andrew Thompson – MHRA
11:00	**Comparison of different Benefit-Risk methodologies** Professor Johan Bring – Statisticon AB
11:30	**LUNCH**
13:00	**A Structured Approach with Focus on Transparency, Clinical Significance and Visualization** Dr. Sinan B. Sarac – National Board of Health
13:30	**Post-marketing surveillance of drug safety in 2012: The EU Regulatory Framework** Dr. Doris Stenver – Danish Medicines Agency
14:00	**Considerations for Implementing a Structured Benefit Assessment in Product Development** Dr. George Quartey – Genentech
14:30	**TEA/COFFEE**
15:00	**Cost/benefit evaluations in road safety… and in pharmaceutical pricing and reimbursement.** Professor Ulf Persson – Swedish Institute of Health Economics
15:30	**Benefit-Risk Modelling of Pharmaceuticals: Where are we going?** Professor Lawrence Phillips
16:00	**Panel Discussion** Lawrence Phillips, Andrew Thomson, George Quartey and Ulf Persson
17:00 Close	chaired by Carl-Fredrik Burman

For full details and to register go to www.efspi.org