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The Swedish Society for Medical Statistics (FMS) and the Danish Society for Biopharmaceutical Statistics (DSBS):

Statistical Issues in Medical Statistics
4th joint workshop
27 April 2010

Abstracts

Professor Deborah Asbhy, Imperial College: *Bayesian Statistics: are theoretical advances changing practice in the pharmaceutical industry and regulation of medicines?*

Bayesian methods are increasingly being used across many stages of drug development. This talk will give a brief introduction to Bayesian methods and their applications in medical research, and in particular in clinical trials. Examples will be used from early stage drug development through to the formal evaluation of risks and benefits of medicines, showing how Bayesian methods have already been used in practice, and where they may be used increasingly in the future both within the pharmaceutical industry, and in drug regulation.

Dr. Mikael Andersson, Stockholm University and the Swedish Institute for Infectious Disease Control: *Swedish experience of the pandemic influenza 2009-10*

On June 11th 2009, WHO declared the newly emerging H1N1 strain of influenza a pandemic, the first since the Hong Kong flu in 1968-69. Sweden immediately decided to offer all citizens two doses of the new vaccine against the disease. The vaccination program started in mid-October, focusing first on specific risk groups, and by the end of the year 61 percent of the population was vaccinated. The first Swedish case of the new influenza was diagnosed on May 6th and the first fatality reported on August 31st, but the peak of the outbreak occurred in mid-November. So far, 11 000 laboratory-verified cases have been reported to the Swedish Institute of Infectious Disease Control, of which 1456 were hospitalized and 27 died. This talk will review some of the epidemiological experience of the new influenza in Sweden, especially in relation to some of the neighbouring countries.

Professor Henrik Madsen, Technical University of Denmark: *PK/PD modelling using stochastic differential equations*

This talk will describe the advantages of using stochastic differential equations (SDEs) for PK/PD modelling, as compared to the ordinary differential equations most often used today. It will be argued that the SDE based approach is needed in order to obtain reliable conclusions based on data. Finally, it will be shown how stochastic differential equations can be used to identify unknown functional relations. The talk considers also the mixed effects modelling using SDEs, and will contain examples from local pharmaceutical companies.

Dr. Anna Rydén, AstraZeneca R&D: *Patient Reported Outcomes (PROs) — an industry perspective*

Patient reported outcome (PRO) measures are frequently used in clinical trials for evaluating treatment efficacy, and the use of PROs is also expected to increase. The FDA Guidance for Industry, finalized Dec 2009, documents the process for developing and modifying a PRO to be regarded validated and fit for purpose. This iterative process includes a combination of qualitative and quantitative methods, and calls for the cooperation between Statistics and Outcomes Research. Although the FDA Guidance focus is on PROs for backing up commercial claims from the pharmaceutical industry, the methodological requirements should be considered also within academic research.

Executive Director Silvana Cappi, Ferring: *Running a virtual department through outsourcing*

Ferring Pharmaceuticals' Global Biometrics department employs 20 people in the fields of Data Management, Statistical Programming and Biostatistics. The Department is based at Ferring's International PharmaScience Centre in Copenhagen.

Ferring is a successful research-oriented midsize pharmaceutical company with several projects in development and in the pipeline. To cope with the increasing workload, strict regulations, ambitious timelines and high productivity, the Department increases its resources through a range of alliances with several external partners such as overseas and local CROs, EDC providers and independent consultants in combination with a high performance in-house team.

This paper discusses the main challenges of running a virtual department, building and maintaining successful partnerships and its value in contributing to achieve the main goal of reducing time to market.

Dr. Gary Jansson, Manager Biostatistics, Quintiles: *The Uppsala biostatistics landscape in the 2000's — an outsourcing perspective*

The closure of the Pharmacia R&D facility in Uppsala in 1998 caused some frustration and worries for the future among the employees. The situation at that moment and what happened afterwards, including a glance at the future as well, will be described from a biostatistics perspective. The biostatistical job market, the current work load, and the change in outsourcing patterns seen in this region, will be discussed. The information that forms the basis for the presentation has been collected from the major Uppsala biostatistical employers using a simple questionnaire.

Dr. Peter Nordström, Medicon Valley Academy: *Future prospects for Medicon Valley*

The ongoing restructuring and rationalisation measures and the global financial crisis have certainly influenced the life science sector in Medicon Valley. As a result, we have seen both staff reductions and companies that have had to close altogether. Despite the tough times, Medicon Valley is still standing strong with a robust pipeline portfolio, numerous new start-up companies and newly established investment funds. The companies in the cluster has so far managed to adjust for these redundancies and maintain most of the competence and knowledge within Medicon Valley and the recent strategic investments in the region worth billions of Euro, provide a robust platform enabling Medicon Valley to continue being a stronghold within the life science sector.