Joint Meeting of the MHRA and the European Federation of Statisticians in the Pharmaceutical Industry

March 29th & 30th 2010

Royal Statistical Society, 12 Errol Street, London, EC1Y 8LX

Statistics at the frontier of drug development

The meeting intends to provide a unique opportunity for discussion amongst industry, regulatory and academic scientists. Topics range from risk assessment to modelling and simulation. Contributions have been sought from speakers from industry, regulatory and academia. In all sessions and the panel discussion there will be ample opportunity for attendees to participate in open discussions about industry standards and regulatory guidance.

Program

Monday March 29

12:00 – 13:00	**Registration and welcoming lunch**
13:00 – 13:15	**Opening by the program chairs** Rob Hemmings, MHRA Kit Roes, Chair Scientific Committee of EFSPI
13:15 – 15:00	**Quantification and Evaluation of Risk** Chair: Harry Southworth, Astra Zeneca Accurate evaluation of risks associated with a new drug, and the ability to judge the importance of these risks, is an increasingly important part of the drug development process, particularly in the context of high-profile drug safety issues in recent years. The application of exploratory statistical methods to safety data can identify and quantify risks and lead to greater understanding of the safety of drugs. This session will provide academic, industry and regulatory views on approaches to the evaluation and communication of such risks. **Speakers:** Andy Grieve (King's College, London), Joe Whittaker (Lancaster University), David Wright (MHRA) – discussant.
15:00	**Break**
15:30– 17:30	**Quantitative approaches to benefit/risk assessment** Chair: Rob Hemmings, MHRA Research is ongoing into whether increased use of quantitative methodology can enhance regulatory decisions taken on benefit-risk, both in terms of scientific validity and in terms of consistency and transparency to stakeholders. The need for this research will be motivated and ongoing activities will be reviewed. Speakers from regulatory and industry will review available case studies and examples and will comment on the future landscape for benefit-risk assessments. **Speakers:** Christy Chung-Stein (Pfizer), Rob Hemmings (MHRA) and Mike Colopy (GSK).
18:00	**Networking Reception at the Royal Statistical Society**

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Tuesday March 30

8:30 – 10:00 **Roles and responsibilities of statisticians in improving dose selection and End of Phase II decisions**
Chair: Simon Day, Roche.

The session will consider whether current standards for Phase II development are 'fit for purpose' in terms of the evidence base for both dose-selection and go, no-go decision making prior to initiating confirmatory development. The role of the statistician in promoting high-quality and informative exploratory development will be reviewed, factors limiting the input of the statistician discussed and the role of the regulatory system in helping the sponsor statistician will be considered.
Speakers: Ekkehard Glimm (Novartis), David Wright (MHRA)

10:00 **Break**

10:30 – 12:00 **Uses and acceptability of modelling and simulation throughout Drug R&D**
Chairs: Gerd Rosenkranz, Novartis; Christoph Gerlinger, Bayer-Schering

The session will exemplify the spectrum of modelling and simulation in the drug development process. Case studies will be presented that cover a broad range of applications which were relevant for the sponsors internal decision making or played an important role in the approval of new treatments. Representatives of the EMEA will provide their views on the topic.
Speakers: Rolf Burghaus (Bayer-Schering), Bengt Hamren (Novartis) and Manolis Efthymios/Franz Koenig (EMEA).

12:00 – 13:00 **Lunch**

13:00 – 14:30 **Statistical and methodological topics in biomarker based patient selection and stratification strategies**
Chair: Nathalie Fretault, Sanofi-Aventis.

Personalized medicine involves a change of paradigm for development of drugs. Compounds are expected to be beneficial for subset of patients to be identified according to genomic characteristics or associated biomarkers. The Impacts on drug development will be discussed and reviewed. Regulatory feedback based on case studies will be presented.
Speakers: Werner Brannath (Medical University of Vienna), David Brown (MHRA) and Birgitte Søgaard (Lundbeck).

14:30 **Break**

15:00 – 16:00 **Regulatory statistical and quantitative science**
Chair: Kit Roes, EFSPI and University Medical Center Utrecht

PANEL: Simon Day, Andy Grieve, Rob Hemmings, David Brown, David Wright, Norbert Benda

A selection of hot topics, developed by the organising committee with input from attendees to the meeting will be put for discussion to a panel of experienced industry and regulatory statisticians to understand the reasons behind, and to highlight improvements that can be made to, industry practice and regulatory guidance. Don't agree with a regulatory guidance document? Have a question about an ongoing development programme? Need to reconcile differences between European and US standards? Want to know about regulatory practices and procedures? This is your chance to ask!

Registration after 22nd February €300