EFSPI Newsletter April 2011

In this newsletter:

EU Statistics Leaders Meeting

The second meeting of Statistical Leaders within Europe will take place on 8th June. Four key topics will be discussed: "Accreditation of pharmaceutical statisticians", "Model-based drug development", "Comparative drug effects & network meta-analysis", and "Totality of evidence, can we make better use of resources". Contact Lesley France (email: Lesley.France@AstraZeneca.com) for further information.

Accreditation of Pharmaceutical Statisticians

EFSPI is developing a proposal regarding the introduction of a European professional level accreditation for pharmaceutical statisticians. Currently a variety of national statistical associations have accreditation for statisticians, which aims to set standards but no European system exists and no national system focuses exclusively on pharmaceutical statisticians. A European wide accreditation system would enable a standard to be defined for statisticians working in the Pharmaceutical Industry, and be based on relevant education and professional experience. A proposal for how the scheme would work will be discussed at the EU Statistics Leaders meeting. Contact Egbert Biesheuvel (Email: egbert.biesheuvel@merck.com) for further information.

Scientific Affairs

A successful International Symposium on Biopharmaceutical Statistics (ISBS) conference was held in Berlin in early March. EFSPI jointly organized two sessions with the EMA on Sub-groups and Regulatory Statistics in Europe at the conference.

EFSPI is currently organising a European Statistical Meeting with SBS/BVS (Belgium) and PSDM (Netherlands) on **Advances in the Treatment of Missing Data**. This will be held in Brussels on Friday 18th November 2011. Geert Molenberghs and James Rogers have already kindly agreed to present at the meeting. If you would like to present also, please contact Nigel Howitt (Email: howittnigel@praintl.com).

Regulatory Affairs

EMA released a draft reflection paper on "Use of active controls in clinical trials where placebo deemed ethical" (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/01/WC500100710.pdf). EFSPI submitted comments (http://www.efspi.org/index.php?p=PUBLICATIONS&fid=44) and participated in an EFPIA working group reviewing the paper. There was Industry consensus that the need for an active comparator must be considered on a case-by case basis. In general, the specific treatment guidelines are the best place to elaborate these situations, and these should provide flexibility where appropriate consistent with this Reflection Paper. In addition, the multiplicity issues could significantly complicate the study design depending upon the study design, objectives, endpoints and hypothesis strategies.

The regulatory work plan for 2011 aims to review the draft EU guideline on the use of subgroup analyses in confirmatory clinical trials (draft expected in 2011), the draft EU annex to the guideline on conditional marketing authorisation on methodological considerations (draft expected Q2 2011), the draft FDA guidance on multiple endpoints (expected in 2011), and the draft FDA guidance on providing regulatory submissions in electronic format: analysis datasets and documentation (expected in 2011). Contact Christoph Gerlinger (email: christoph.gerlinger@bayer.com) for further information.

Other News

If you want to hire a statistician, EFSPI is offering the first three adverts free on its website. If you are interested, go to the "Advertisements" area on the EFSPI website at www.efspi.org and view the "Job Postings" for more information.

The next EFSPI Council meeting will take place on 9th June 2011, following the Statistical Leaders meeting, in Uxbridge UK.

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