EFSPI Newsletter December 2011

In this newsletter:

EFSPI Council News

The EFSPI Council met face to face on 6th December at MSD in the Netherlands. The meeting began with a review of the EFSPI finances where a loss of ~ ten thousand Euros is predicted for 2011. Fortunately this loss can be covered by the EFSPI reserves. The council has reviewed options for minimising expenses in 2012 given the continued tough economic climate, and for keeping membership and meeting fees cost-effective.

EFSPI is the European umbrella organization bringing many of the statistical associations across Europe together to align on important scientific and statistical matters in the Pharmaceutical Industry, and to collaborate and discuss emerging methodologies and best practices. Look out for more information in 2012 highlighting the value of EFSPI to the national associations and EFSPI's strategic plans.

Scientific meetings were summarized as were recent regulatory workshops, see below for more information.

Finally, the constitution has been updated to include a reference to the new treasurer role introduced a year ago, plus some minor administrative changes. The updated constitution will now be submitted to each member country for formal approval.

EU Statistics Leaders Meeting

Plans are under way for the third annual EU Statistics Leaders Meeting. **Stefan Driessen** from Abbott is chairing the meeting. If anyone has any specific topics for discussion then please email Stefan directly: **stefan.driessen@abbott.com.** Special attention will be paid to the changing environment for statisticians in the pharmaceutical industry with its challenges and opportunities and how to manage this within the EU context.

A reminder that all the materials from the previous 2 EU Statistics Leaders meetings held in 2010 and 2011 are available on the EFSPI website:
http://www.efspi.org/index.php?p=EFSPI%20activities&fid=399

News from National Groups

For an update on the activity from each national organization, please see the EFSPI website: **www.efspi.org**.

Update on Special Interest Groups (SIGs)

EFSPI are pleased to announce the PSI Biomarker SIG will be expanded to include EFSPI interested parties. **Anyone wishing to join the mailing list or the organising committee for this SIG can contact Martin Jenkins, Martin.Jenkins@astrazeneca.com**.

The SIGs have all had a busy and productive 2011 as summarized below:

The **Medical Devices SIG** (leader = Roland Marion-Gallois , roland.marion-gallois@medtronic.com) have been meeting on a monthly basis to keep abreast of developments with medical devices, and recently presented at the "SFdS Biopharmacie et Santé" conference.

The **Health Technology Assessment SIG** (leader = Chrissie Fletcher, fletcher@amgen.com) has updated their HTA handbook for statisticians (link: http://www.psiweb.org/index.php?p=resources&fid=1037#), written 2 publications in Pharmaceutical Statistics relating to subgroup analyses in HTA and indirect comparisons, held round table discussions with 2 experts in the HTA field, Prof Andy Briggs and Dr Neil Hawkins, initiated discussions with ISPOR president to seek opportunities to collaborate, and contributing to planning of 2 parallel sessions at the 2012 PSI Conference on HTA (link to program: http://www.psiweb.org/index.php?p=committees%20and%20subgroups&sid=3).

The **Epidemiology and Safety SIG** (leader = George Quartey, george.quartey@roche.com) has written 3 publications in Pharmaceutical Statistics relating to measuring drug exposure and effects in pharmacoepidemiology, bias minimisation in pharmacoepidemiology and Bayesian approaches to safety analyses, and contributing to planning a parallel session at the 2012 PSI Conference on Safety.

The **Modelling & Simulation SIG** (leader= Michael O'Kelly, michael.okelly@quintiles.com) has written 2 publications in Pharmaceutical Statistics relating to predictive event modelling in event driven trials and reflections of modelling and simulation in Pharmaceutical Industry, and held 3 meetings.

The **Biomarker SIG** (leader = Martin Jenkins, Martin.Jenkins@astrazeneca.com) has written a publication in Pharmaceutical Statistics relating to Statisticians perspective of biomarkers in drug development and held 1 meeting.

The **Toxicology SIG** (leader = Jim Saul, Jim.Saul@covance.com) has written 2 publications in Pharmaceutical Statistics relating to genetic toxicology and statistical methods used in animal toxicology, and ran a 2 day workshop. The SIG run the workshop every ~18 months.

The new Benefit-**Risk SIG** is currently being formed. Please contact Ian Hirsch (email: Ian.Hirsch@AstraZeneca.com) if you are interested to join this SIG.

Anyone wishing to view any materials from these SIGs can view via the EFSPI website www.efspi.org.

Scientific Meetings

The European Statistical meeting in Advances in the treatment of missing data (18-Nov-11) was fully booked. A total of 98 statisticians attended the meeting in Waterloo, Belgium. The meeting was a

great success and the presentations were well received. A summary of the meeting, including a link to the slides, is available on the EFSPI website: http://www.efspi.org/index.php?p=news&fid=1

For 2012 the following EFSPI meetings are planned:

- Benefit and risk (May 2012), partnering with the Swedish Society for Medical Statistics (FMS) and the Danish Society for Biopharmaceutical Statistics (DSBS)

- Modelling & simulation (Sept 2012), partnering with the Modelling & Simulation SIG

- Subgroup analyses (Nov 2012)

Regulatory Update

On the 18th November 2011 the EMA held a workshop to discuss subgroup analyses in clinical trials. The meeting was chaired by Bruno Flamion who is a former chair of the EMA Scientific Advice Working Party (SAWP)and speakers included Rob Hemmings, the head statistician at the UK regulatory agency and current Chair of SAWP, Armin Koch from Hannover Medical School (formerly from the German regulatory agency) and Sue-Jane Wang, from the FDA. The day was split into 4 sessions:

- The regulators setting the scene with current guidelines and expectations regarding subgroup analyses in regulatory decision making, with a summary from Industry of key recommendations for consideration in the new guideline on subgroup analyses currently being drafted
- Recent methodologies addressing multiple testing and adaptive design strategies were presented and a variety of case studies discussed which have been used as confirmatory subgroup analyses for regulatory decisions
- Use of subgroup analyses in meta-analyses and considerations of subgroups from an HTA perspective then followed, with further case studies being discussed highlighting how subgroup analyses have been used to "rescue" a failed trial or improve the benefit-risk in a subgroup of the overall population
- Q&A session with final remarks

Materials from this meeting can be found on the EMA website:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2011/10/event_detail_000536.jsp&mid=WC0b01ac058004d5c3&jsenabled=true

A two day joint EMA-EFPIA workshop focusing on the role and scope of modelling and simulation (M&S) in drug development from both the regulators and developers perspective, was held 31st Nov – 1st Dec 2011 at the EMA in London. Day 1 initially focused on the view points of the EFPIA, FDA, EMA and PDMA. This was followed up by a selection of interesting examples where M&S had been successful and unsuccessful in meeting the regulators' expectations. Day 2 examined the advantages and challenges of using M&S to support decision making through case studies. This was divided into four key areas:

- M&S in early development
- Clinical pharmacology and dose finding
- A tool to bridge efficacy and safety data in some special populations
- To optimize the design and analysis of confirmatory trials.

The workshop highlighted that M&S has a key role in improving the efficiency of the drug development process. The regulators clearly encourage the use of modelling and simulation in drug

development. Their expectations depend on the likely impact on the regulatory decision. An example of high impact, for which seeking scientific advice is advised, is the use of M&S to replace data in support of efficacy or safety. Medium impact may be the use of intermediate doses in a confirmatory trial that has not been studied in phase 2, and low impact is the use of M&S for internal sponsor decisions where phase 3 results will supersede the M&S.

Other News

If you are currently seeking to hire a statistician and wish to post a job advert, see the "Advertisements" area on the EFSPI website at www.efspi.org and view the "Job Postings" for instructions. EFSPI are offering one free advert for every 3 adverts posted on the website.

To add your e-mail address to the EFSPI mailing list, click on "Sign up to our newsletter" on the homepage of the EFSPI website at www.efspi.org.

✡ Happy Christmas and best wishes for the New Year.✡

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EFSPI