



EFSPI Newsletter April 2014

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Regulatory Update

Post-Authorisation Efficacy Studies (PAES)

EMA has established a working group to develop a new scientific guideline on post-authorisation efficacy studies (PAES). EFPIA are establishing a working group to develop an EFPIA position and the PSI/EFSPI regulatory committee will also be developing an EFSPI position including collaborating with EFPIA.

REMINDER: Draft guideline on the investigation of subgroups in confirmatory clinical trials

Please don't forget to review the draft guideline EMA have published on the investigation of subgroups in confirmatory clinical trials (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/02/WC500160523.pdf). When commenting **please use** the official template (see http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=W500004016). This makes collating and consolidating them much easier. Please return comments by the **7th May 2014** to Alan Phillips (Alan.Phillips@iconplc.com). A meeting to discuss the draft guideline will take place on the afternoon of Wednesday 14th May at the end of the PSI Conference.

REMINDER: Meeting with MRHA Statisticians.

The EFSPI/PSI Regulatory committee is meeting with some of the MRHA statisticians in June. In preparation for this meeting we would like to receive questions from EFSPI/PSI members that you would like discussed with the MRHA statisticians. Please can you send your questions to Frances Lynn (Frances.Lynn@biogenidec.com) by the **7th May 2014**.

SIG of the month: Medical Devices

Medical devices are defined as any healthcare products that do not achieve their principal intended purpose by chemical action or by being metabolized. This definition encompasses products that vary greatly in their complexity, purpose and mode of action. It includes simple crutches as well as complex diagnosis devices such as endoscopy capsules. From a regulatory point of view, the development of medical devices is different from that of drugs, e.g. the market authorization for devices is delivered by country Notified Bodies through the CE mark, while it is delivered by the EMA in the case of drug products through the ICH guidelines.

All the specificities related to the medical device industry led to the launch of the Special Interest Group (SIG) on Medical Device in 2010. The purpose of this SIG is to provide a discussion platform for statisticians working in the Medical Device industry and to address specific needs in this field. The main aims of the group are the following:

- *To create visibility on biostatistics activities for medical devices,*
- *To strengthen methodological aspects in the development of medical devices,*
- *To create an expert group identified by authorities,*
- *To share Good Statistical Practice.*

In the last few months activities of the SIG were mainly focused on regulation topics. The group has extensively reviewed and commented the European directive on the regulatory framework for medical devices (COM(2012)542 final). As result of discussions that were held within the SIG, a letter was sent to the European parliament to share the group's expertise. From the SIG standpoint, regulation for medical devices development should shift more towards the drug development regulations and biostatistics-related topics should have a higher importance in Medical Device regulation. Other topics covered in the last meetings were the EMA initiative on Clinical Trial Data Transparency, the review of the concept paper for ICH-E9 and the presentation on the PARENT initiative to improve and harmonize the quality of patient registries.

These discussions are opportunities to share experience/concerns between statisticians from companies or independent consultants throughout Europe working in different therapeutic area.

The objectives of the Medical Device Group for 2014 are to gain visibility and to share relevant information on Medical Device industry. In this scope, the group was presented during the last EFSPi Statistical Leaders Meeting and is currently developing web platforms. People interested in the SIG can access the group through the LinkedIn interest group: *Medical Device Industry Statisticians*.

The Medical Device group is working through monthly teleconferences of an hour. For further information on the Medical Device SIG or to join the mailing list please contact roland.marion-gallois@medtronic.com.

EFSPI is planning for two scientific meetings in 2014. The first event is on HTA and hopefully it will continue the sequence of successful meetings on this topic, it is planned for September. The second event will be focused on dose finding studies, including modelling approaches like MCP-Mod, and is planned for November.

As a reminder, EFSPI will have a shared session with the PSI on the new subgroup guideline ([see regulatory update](#)) on May 14 in London.

We regret that Nigel Howitt (PRA International) has decided to stop being member of the Scientific Committee, but we also want to thank Nigel for his significant contributions to many meeting over the years as well as being the chairman of this committee in the past.

As mentioned in the previous newsletter, the Scientific Committee is looking for new candidates who are willing to join our committee. We organise European Scientific meetings and provide a platform for key opinion leaders from regulatory, academia and industry to speak and we have a successful track record (http://www.efspi.org/index.php?p=EFSPI_ACTIVITIES&fid=19). If you are interested or want to know more, please contact our chair Egbert Biesheuvel (Egbert.biesheuvel@merck.com)

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5th EFSPI Statistical Leaders Meeting

EFSPI is organizing the 5th EU Statistical Leaders Meeting. The meeting will be held in Basel (at the Roche facilities) on Wednesday, June 11, 2014. Over fifty Leaders have received a personal invitation to this meeting. The purpose of the one-day meeting is to consider and discuss the (new) developments in our area and the impact on our profession. The outcome of the meeting will help direct the strategy for EFSPI.

At last year meeting a lot of attention to the topic of Clinical Trial Data Transparency was given and this year it will be again an important topic for discussion. This year two Special Interest Groups will present their topical area: the new SIG Integrated Data Analyses and the SIG Pharmacology-Epidemiology. In the afternoon an interactive meeting will be held on recent developments like the EMA parallel scientific advice from Regulators & Health Technology Assessment bodies, and the EMA work group on PAES (Post Approval Efficacy Studies). These developments will bring new types of data and study designs, such as observational studies, pragmatic trials, and also come with data more mirroring medical practice than the data from typical RCTs. As one can imagine, this brings naturally the trending topic of Real World Data, and Big Data, to the table.

For more information about this meeting, or specific questions on these topics you would like to see addressed at the meeting, and/or any other comments/question on this Forum, please contact Stefan Driessen (stefan.driessen@abbott.com).

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Other news and events

Reminder: RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry

This award is now in its fourth year and we encourage managers of statistics groups within the industry to consider nominating one or more of their direct reports. The nominee does not need to be a member of PSI or the RSS. In addition, the nominee, and/or the organisation for which he or she works, may be based anywhere in the world.

The award recognises a most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry.

The nomination forms are available via the RSS website (<http://bit.ly/1lha9Wd>) with a submission deadline of **23rd May 2014**. If you have any questions about the Award or how to make a nomination, please feel free to contact Byron Jones at byron.jones@novartis.com.

**PSI 2014 Conference, The Tower Hotel, Tower Bridge, London,
Sunday 11 to Wednesday 14 May 2014**



For further information about the conference please [click here](#) or to register your place at the conference please [click here](#). As well as the conference you can register for the Health Economics workshop on the 11th May 2014 through the www.psiweb.org. (The course is not restricted to conference delegates.)

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The World of Statistics

The [World of Statistics](#) currently has a total of 2,362 participating organizations from a whopping 129 countries. As a reminder, the objectives of the World of Statistics are:

- Increasing public awareness of the power and impact of statistics on all aspects of society

- Nurturing statistics as a profession, especially among young people
- Promoting creativity and development in the sciences of probability and statistics

Science Careers, a publication that provides a variety of content to assist scientists of all disciplines, backgrounds and experience levels navigate their career path, this week published online an article highlighting the [growing opportunities in the field of statistics](#). The first-ever Women in Statistics Conference will be held May 15-17 in Research Triangle Park, which is located near Raleigh, North Carolina in the United States.

[Significance](#) and the [Young Statisticians Section](#) of the Royal Statistical Society are once again hosting a competition to promote good writing about statistics. This time, the rewards are even greater! All budding writers within the first 10 years of their statistical career are invited to submit articles which would be suitable for *Significance* magazine. Click [here](#) for more information, the closing day is 30th May 2014.

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And finally.....

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.

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