



## EFSPI Newsletter March 2014

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### Regulatory Update

#### 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](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](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 7<sup>th</sup> May 2014 to Christoph Gerlinger ([christoph.gerlinger@bayer.com](mailto:christoph.gerlinger@bayer.com)). A meeting to discuss the draft guideline will take place on the afternoon of Wednesday 14<sup>th</sup> May at the end of the PSI Conference. More details will follow in April.

#### **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](mailto:Frances.Lynn@biogenidec.com)) by the 7th May 2014.

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## **SIG of the month: Biomarkers**

The Biomarker Special Interest Group (SIG) was formed in early 2008. Many of the SIG's events attracted attendees from across Europe and far beyond on occasions. The group was set up to enhance knowledge of the statistical methods and study designs related to the use of biomarkers in pharmaceutical development within the statisticians who are employed by the Pharmaceutical Industry and also to provide a forum for the sharing of experience between them.

Over the past 6 years the Biomarker SIG has held many face-to-face scientific meetings and conference sessions on a wide variety of biomarker related topics including:

- The use of biomarkers in early clinical development
- The use of Omics and high dimensional biomarker data
- Experimental design for biomarker related studies in late stage development (including personalised medicine approaches)
- The validation and qualification of biomarkers, including for diagnostic development
- Practical challenges in the use of biomarkers
- Translation of pre-clinical and safety biomarkers to the clinic

Our meetings have always been free to attend (Except PSI Conference Sessions) and hosted by a pharma company to-date within UK (GSK, Roche, Amgen and MedImmune/AstraZeneca has all generously hosted one or more of these meetings). Attendance has typically been in the range of 30-50 statisticians. Slides from past meetings and further information can be found on the [Biomarker SIG page on the PSI website](#). We can also be found on [LinkedIn](#).

The SIG have written a [review paper](#) in Pharmaceutical Statistics giving "*A Statistician's Perspective on Biomarkers in Drug Development*" and collated an associated reading list of the relevant literature. In September 2013 the SIG ran a 2 day residential training course for 20 statisticians from across Europe on "Statistical Issues in the Use of Biomarkers," covering methodological aspects and also featuring a hands-on-session. We hope to re-run the course in the future – please get in touch if you are interested in attending the course. Our next event is a parallel session at the 2014 PSI conference in London on the reporting of biomarker studies in the scientific literature. We plan to hold bi-annual face-to-face meeting as has been done in the past. This year we aim to run a face-to-face meeting on *Biomarkers Hands-on-workshop/"Biomarker Hackathon"* and an on face-to-face meeting on *Big Data in Biomarker Development*. Both of these meetings are currently scheduled to be held in Cambridge (UK) (but we are open to venues facilitated by you so please get in touch). We are open to your ideas/topics for future events, especially during the 2015.

The Biomarker SIG is run by a core organising committee of 10 individuals who actively develop SIG events and activities. Further subject matter experts are brought in on a topic-by-topic basis to speak at meetings or courses or to contribute to documents. In addition the SIG mailing list contains over 150 further statisticians (pharmaceutical and academic) who we keep up to date with our plans and who attend our events. This mailing list includes members from Belgium, Denmark, France, Germany, Italy, the Netherlands, Norway, Sweden, Switzerland, and the UK as well as some in the USA and meeting attendance has reflected a similar variety of nationalities.

For further information on the Biomarker SIG or to join the mailing list please contact Athula Herath (Chair Biomarker SIG, [heratha@medimmune.com](mailto:heratha@medimmune.com)).

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## **Scientific Update**

EFSPI is planning for two scientific meetings in 2014. The first event is planned for September to discuss dose finding studies, including modelling approaches like MCP-Mod. A second meeting is planned for November on HTA. In addition EFSPI will have a shared session with the PSI on the new subgroup guideline ([see regulatory update](#)) in May in London.

The Scientific Committee of EFSPI 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](http://www.efspi.org/index.php?p=EFSPI_ACTIVITIES&fid=19)). If you are enthusiastic, pro-active and are willing to help us organise successful scientific meetings, we are looking for you! If you interested or want more information, please contact the Chair of the committee Egbert Biesheuvel ([Egbert.biesheuvel@merck.com](mailto:Egbert.biesheuvel@merck.com)).

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## **Other news and events**

### **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>).

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](mailto: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](http://www.psiweb.org). (The course is not restricted to conference delegates.)

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## **EFSPI Council Update**

Welcome to 2 new Council members: **Marissa Bacchi** representing Switzerland replacing Fred Sorenson and **Maylis Coste** representing France replacing Françoise Tondu. A huge thanks to Fred and Françoise for all their contributions to EFSPi over many years.

The [EFSPi goals for 2014](#) were agreed, and the [3-year EFSPi strategic plan](#) for 2013-2015 and the associated activities remain on track as planned. EFSPi continue to keep a close eye on their budget, and have one major additional expense planned in 2014. As discussed and agreed in 2013 EFSPi are proceeding to redesign the EFSPi website. Following a review of possible external vendors, the most cost-effective solution is to award the development of the new website to the EFSPi executive office. This will enable many of the existing EFSPi administrative tasks to be more fully integrated with managing the EFSPi website. EFSPi hope to launch the new website before the end of the year.

The EFSPi/PSI data transparency working group is enabling the EU Statistics community to proactively plan how to best engage as the environment continues to evolve, especially important given the final EMA policy on access to clinical trial data will be published this year. The Special Interest Groups (SIGs) have strong engagement and support, they are enabling multiple stakeholder groups to have important scientific discussions, and they are ensuring statisticians have a voice at the table. The Council wishes to express their gratitude to all those individuals who are members of the SIGs and their hard work and efforts. The Council is looking forward to finalizing the details of the EFSPi Statistics Leaders meeting taking place on the 11<sup>th</sup> June 2014.

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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 30<sup>th</sup> 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](http://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.

To view previous newsletters please see the EFSPI website in the "News" area.

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