



**European Federation of Statisticians in the Pharmaceutical Industry**  
Representing Statistical Associations in Europe

## EFSPI Newsletter February 2015

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### **New EFSPI Website**

EFSPI are pleased to announce the release of its new website. The new website was launched on February 10th, 2015 and is available at the usual URL <http://www.efspi.org>.

Several new features have been added, among which specific pages (with both public content and secured private working areas) for the different SIGs and EFSPI working parties. The site content has been reviewed and updated, and the updating process will continue over the next weeks to provide you the most up-to-date information.

Thanks to KSAM for re-designing the new website, and for Francois Aubin for project managing the website activities, which were achieved to the planned budget and schedule. EFSPI Council are pleased with the enhanced interface and hope you enjoy visiting the site regularly to obtain latest news, view upcoming scientific meetings, access presentations from previous scientific meetings, read EFSPI reports and position papers, and keep up to date with the activities of the Special Interest Groups (SIGs).

Feedback on the new website is welcomed, please contact Francois Aubin (email: [Francois.Aubin@vlsworldwide.com](mailto:Francois.Aubin@vlsworldwide.com)).



**WELCOME TO THE NEW EFSPi WEBSITE**  
THE NEW WEBSITE WAS LAUNCHED ON 10<sup>TH</sup> FEBRUARY 2015  
WE HOPE YOU WILL FIND IT OF INTEREST AND WILL VISIT IT REGULARLY



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**SOCIAL NETWORK**



## **Scientific Update**

EFSPI will be involved in four meetings in 2015:

- A joint meeting on **Health Technology Assessments** with the BBS in Basel on the 23rd June 2015
- A joint meeting with the PSI on **Estimands** in September,
- A meeting on Late stage **Dose Finding studies in Clinical Studies**, in September – October with potential location Brussels,
- A meeting on Biomarkers & Subgroups, in November and will have a special theme – more information will follow.

Dates and locations will be confirmed in subsequent newsletters and available on the EFSPI website. In addition, the Scientific Committee will meet with representatives of all national organisations to pull together a summary of all planned meetings taking place in 2015 including proposed topics and agenda's. We hope this will provide you with a better overview of all important dates and topics of meetings within all of the EFSPI associations.

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### **6<sup>th</sup> EU Statistics Leaders meeting**

This year the 6<sup>th</sup> EU Statistical Leaders Meeting will be held Wednesday July 1 in Brussels, kindly hosted by MSD. The agenda is in full preparation and was discussed already with the Statistics Leaders. There is great interest to discuss the challenges for companies in dealing with areas as Benefit-Risk and Real World Evidence not only from a scientific angle but very much from an organization point of view. Also the hot topic of "Estimands" (for which there is an ICH working group with EFSPI representation) was listed for such a discussion. No doubt the strategic and organizational aspects will again play a key role in the discussions of this group that has shown to be very helpful for EFSPI in defining their strategy. In order to augment the impact and coverage in the EU pharmaceutical statistics community the meeting will also try to engage Statistical Leaders from companies not yet represented and as such be even better positioned to network and exchange experiences and ideas across the EU Statistics community.

This year's Organizing Committee consists as of now of Chrissie Fletcher, Hans-Ulrich Burger, William Malbecq and Stefan Driessen. For more information about this meeting, or any other comments/questions on this Forum, please contact Stefan Driessen ([stefan.driessen@abbott.com](mailto:stefan.driessen@abbott.com)).

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## **Other Upcoming Events**

### **AFP (Germany)**

The APF is organizing a session on Benefit-Risk Assessment during the 61. Biometrisches Kolloquium 15.-18. March 2015 in Dortmund <http://www.statistik.tu-dortmund.de/Biom2015/>. The APF Fall Meeting is planned for November 27<sup>th</sup> 2015 in Ludwigshafen.

### **BIAS (Italy)**

Bias is organising an event on 'Data Visualization in Clinical Research' on the 20<sup>th</sup> March 2015 in Milan, Italy. The agenda will be available soon on the EFSPi website and the event will be held in English.

## **PSI (UK)**

**PSI Training Course: Cross-over trial in Clinical Research**, 4<sup>th</sup> – 5<sup>th</sup> March 2015, Heathrow, London. The emphasis is on practical matters: how should one plan and analyse cross-over trials if one is genuinely interested in finding out the effects of treatment. The approach is grounded in practical pharmacological considerations and unrealistic approaches to adjusting for carry-over will be avoided. The examples are all genuine. Click [here](#) for further details.

**PSI 2015 Conference:** PSI invites you to join us at the 2015 PSI Conference "Relevant **Applications in a Changing Environment**" at **The Millennium Gloucester** Hotel, London between 10 to 13 May 2015. The latest draft of the PSI Conference Session Plan is available to view on the PSI website here [http://psiweb.org/docs/default-source/default-document-library/copy-of-session-plan\\_15jan2015.xlsx?sfvrsn=0](http://psiweb.org/docs/default-source/default-document-library/copy-of-session-plan_15jan2015.xlsx?sfvrsn=0). Please be aware the early bird deadline is fast approaching on **16th February** and places are filling up fast so don't forget to secure your place soon. Need some more encouragement? Then take a look at our short promotional video to hear why some familiar faces will attend: <http://psiweb.org/members/news/news-item/2015/01/20/psi-conference-video>. We're still accepting abstracts for our contributed sessions so please continue to submit them to [PSI2015conference@mci-group.com](mailto:PSI2015conference@mci-group.com). The deadline for abstracts is **2nd March**. We welcome abstracts on any subject but would be particularly interested in the following: Data transparency case studies, Modelling and simulation, Challenges and issues in early clinical development, and Presentations from career young statisticians. If you are a career young statistician (less than 5 years working in the pharmaceutical industry) then there will be a dedicated contributed session for you. This is a great opportunity to gain experience in presenting in a friendly environment and to network with peers at other companies.

## **Austrian–Japan joint Statistics Workshop**

This joint meeting on "Innovative Clinical Trial Designs for Accelerating Medical Product Development" will take place on March 20-27 2015 in Osaka, Japan. Keynote Speakers include Frank Bretz (Novartis Pharma AG, Switzerland) and James Hung (FDA, US). Pre-conference short course on sub group analysis (Alex Dmitrienko), adaptive designs & multiple testing (Peter Bauer, Franz König, Florian Klinglmlüller, Martin Posch), and challenges of clinical trials (James Hung). For more details and registration please visit: <http://statistics.msi.meduniwien.ac.at/hp/jsps2015/>

## **DIA/FDA**

DIA/FDA statistics forum, Apr 20 - Apr 22 2015, Bethesda, US. Featured topics include Biosimilars/Analytical Similarity Adaptive Design, Bayesian Working Group Feedback, Sentinel Initiative and Postmarketing Surveillance, Statistical Issues Related to Health Technology Assessment, Subgroup Analysis, Benefit-Risk, Estimands and Sensitivity Analyses, and FDA and Industry Town Hall. For more information click [here](#).

## **ISCB**

The 36<sup>th</sup> Annual Conference of the International Society for Clinical Biostatistics, which will take place in Utrecht, The Netherlands, August 23-27, 2015 (<http://www.iscb2015.info/>).

The conference is a scientific forum for international exchange of theory, methods and applications of biostatistics in medical research and practice. ISCB 2015 is intended for statisticians, clinicians and members of other disciplines, such as epidemiologists, clinical chemists and clinical pharmacologists interested in the field of clinical biostatistics.

## Multiple Comparisons Procedures Conference

The IXth International Multiple Comparisons Procedures (MCP) Conference will be held in Westin Hotel, Hyderabad, India from September 2, 2015 to September 5, 2015. The conference will cover the latest methodological and applied developments in the areas of multiple comparisons and adaptive designs in clinical trials. There will be pre-conference workshops on September 2 and the main conference will be from September 3 to September 5. Keynote speech will be by Dr. Jason Hsu on "Errors in Multiple Testing Big and Small, Now and Then, More or Less". There will also be a panel discussion on FDA Multiplicity Guidance Document led by Dr. John Scott and Dr. Mohammad Huque of FDA and prominent industry statisticians. Abstract submissions are now open. For further details and submission of abstracts visit <http://www.mcp-conference.org/hp/2015/> or write to Dr. Vishwanath (Mahesh) Iyer [vishwanath.iyer@novartis.com](mailto:vishwanath.iyer@novartis.com).

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## The World of Statistics

The World of Statistics movement has grown to a total of more than 2,364 organizations from countries across the globe. You can view the current participant and country lists by going to [The World of Statistics website](#). To see the events and activities planned for 2015, [click here](#).

**International**—*Significance* magazine has opened its 10-year archives for access by the public. The magazine's volumes 1 through 10 [are available to read](#), free of charge. Further, all magazine content will be made freely available one year after its initial publication. Royal Statistical Society and ASA members and subscribers will continue to enjoy exclusive access to the latest magazine content. [Read more](#).

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## Job Opportunities

For all current recruitment adverts please visit the EFSPi website: [Job postings](#).

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## **Follow us on Twitter and Linkedn**

Get the latest news and updates about EFSPI by following us on Twitter at @EFSPItweet. Also, when you use Twitter to spread the word about EFSPI, be sure to use the hashtag "#EFSPI". You also can follow developments in EFSPI via Linkedn.

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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.

Fun picture of the month (courtesy of [xkcd](#)):

A hand-drawn table with two columns: 'P-VALUE' and 'INTERPRETATION'. The p-values are listed on the left, and their corresponding interpretations are on the right, connected by brackets. The interpretations are written in a casual, humorous style.

<u>P-VALUE</u>	<u>INTERPRETATION</u>
0.001	HIGHLY SIGNIFICANT
0.01	
0.02	
0.03	
0.04	SIGNIFICANT
0.049	
0.050	OH CRAP. REDO CALCULATIONS.
0.051	ON THE EDGE OF SIGNIFICANCE
0.06	
0.07	HIGHLY SUGGESTIVE, SIGNIFICANT AT THE P<0.10 LEVEL
0.08	
0.09	
0.099	HEY, LOOK AT THIS INTERESTING SUBGROUP ANALYSIS
≥0.1	

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