



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

EFSPI Newsletter March 2015

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Regulatory

Regulatory Guidance Documents

EMA's Biostatistics Working Party has published their work plan for 2015

(http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2012/12/WC500136437.pdf). The working party are aiming to release the final Guideline on adjustment for baseline covariates in Q1'15 and the final Guideline on the investigation of subgroups in confirmatory clinical trials in Q3'15.

New drafts of three existing guidance are planned: Revision of the Points to consider on multiplicity issues in clinical trials (Q2'15); Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (Q3'15); Revision of Guideline on data monitoring committees (no date given). The PSI/EFSPI regulatory committee will co-ordinate the review of the draft guidance documents in Europe for EFSPI, and they will submit comments on behalf of EFSPI.

EFSPI Estimand Expert Group

In October 2014 the ICH Steering Committee endorsed a [final Concept Paper](#) with the goal of developing new regulatory guidance, suggested to be an Addendum to ICH E9, which promotes harmonised standards on the choice of estimand in clinical trials and development of a framework for planning, conducting and interpreting sensitivity analyses of clinical trial data. EFPSI held a 1-day

expert group meeting on this topic in February 2015, including 12 representatives from sponsor companies and Contract Research Organisations, and an independent consultant.

The expert group agreed it will be important to communicate and educate both statisticians and non-statisticians in the concepts, terminology and consequences of the choice of estimands for a clinical trial. It will be important to develop and publicise some simple but informative examples which can motivate all involved in clinical trials to become more focussed on the choice of estimands. The expert group considered an estimand as a more detailed statement of the objective, formulated to address the scientific question of interest posed by the trial. Therefore an estimand would include details of the population of interest, an endpoint of interest and a measure of the relevant effect of the intervention. Clearly defined estimands will be needed to make regulatory claims and each estimand involved would need to be linked back to objectives and the study design.

The expert group recognised different stakeholders may be interested in different estimands, in particular distinguishing between regulatory approval and Health Technology Assessment. Two main areas are 'de jure' estimands – sometimes referred to as 'efficacy' – and 'de facto' estimands – sometimes referred to as 'effectiveness'. However this distinction should not be taken too literally as there is some evidence of regulators not finding 'de jure' estimands useful.

The expert group agreed with the Concept Paper that there is not a clear framework for planning and executing sensitivity analyses and that this can lead to inconsistency in regulatory decision-making. While the expert group had differing opinions in certain areas, we all agreed that this is an important area for statisticians to be involved in as we aim to clarify the objectives and applicability of clinical trials. Attendees at the forthcoming PSI conference will be able to take advantage of a session on estimands and sensitivity analyses on the morning of Tuesday May 12th 2015, where statistical leaders from both FDA and MHRA in addition to industry and academia will participate in the discussions.

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Scientific

EFSPI will be holding three scientific meetings in 2015:

- A joint meeting with BBS in Basel on **Health Technology Assessments** with the BBS on the 23rd June 2013, click [here](#) for the flyer and registration details
- A joint meeting with PSI on **Estimands** in September 2015; see also the Regulatory section in this newsletter. More info will follow in the April newsletter
- A meeting on **Dose Finding studies in Clinical Studies** in Q4 2015

EFSPI will be holding for the first time a 1-day **Statistics and Regulatory Workshop** in October/November 2015. Further details will follow in the April newsletter.

In addition, EFSPI is preparing a webinar on Benefit-Risk in June. We will keep you informed if more details are available.

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6th EU Statistics Leaders meeting

The agenda for the 6th EU Statistical Leaders Meeting (July 1, Brussels) is well underway. Almost all speakers/presenters have been confirmed and with topics of how our statistical units are dealing (best) in areas as Benefit-Risk, Real World Evidence, Estimands, and Data Transparency it is expected to become yet again a very useful meeting for the Statistics Leaders to exchange experiences, share ideas, network, and discuss how to best progress our EU Statistics community. This year the intention is to provide even more time for discussions in the one-day meeting by limiting the time for presentations and to have more pre-reads available. Personal invitations are expected to be sent out in April with more details on the agenda and the logistics. For more information about this meeting, or any other comments/questions on this Forum, please contact Stefan Driessen (stefan.driessen@abbott.com).

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SIG (Special Interest Groups) News

Benefit-Risk SIG

The Benefit-Risk SIG had a B-R session together with the APF (Arbeitsgruppe Pharmazeutische Forschung) at the German IBS meeting on March 16, 2015.

The SIG will also present at a B-R session at the upcoming PSI conference on May 11, 2015. The next group meeting of the full SIG will be on May 5, 2015. Anyone interested in the area of Benefit-Risk and would like to join the SIG, please contact B-R SIG Lead Alexander Schacht (schacht_alexander@lilly.com).

Toxicology SIG

The Toxicology SIG is still hoping to hold its next 2 day meeting in October 2015 near Heathrow Airport on the 13th and 14th.

Anyone interested in attending can get in touch with the Toxicology SIG Lead Gareth Thomas for further details (ThomasG@UKOrg.Huntingdon.com).

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Other Upcoming Events

PSI (UK)

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. 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. 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

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 36th 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.

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The World of Statistics

The World of Statistics movement has grown to a total of 2,358 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](#).

On **October 20** this year, the global statistical community will showcase their achievements and their ongoing work to help this vision come true as part of **World Statistics Day 2015**.



The logo for World Statistics Day 2015.

Next month, representatives of The World of Statistics will be meeting with representatives of the UN Statistics Division to discuss how our global community of more than 2,350 participating organizations can get involved in World Statistics Day.

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Job Opportunities

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

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Have you seen the new EFSPi website?

EFSPi are pleased to announce the release of its new website keeping its usual URL <http://www.efspi.org>. Feedback on the new website is welcomed, please contact Francois Aubin (email: Francois.Aubin@venncro.com).



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



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PUBLICATIONS

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EVENTS

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ACTIVITIES

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- The World of Statistics



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- Integrated Data Analysis SIG
- Medical Devices SIG
- Modelling and Simulation SIG
- Toxicology SIG

WORKING GROUPS

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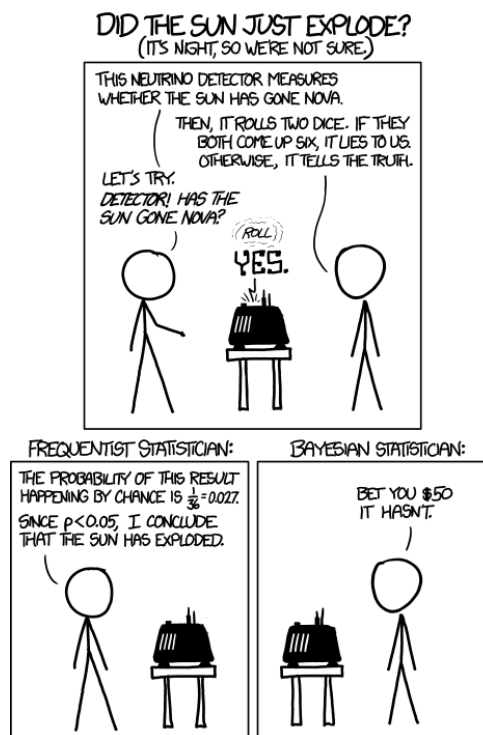
And finally.....

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.

To view previous newsletters please see the EFSPi website in the "[News](#)" area.

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



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Chrissie Fletcher
EFSPi Communications Officer