



EFSPI Newsletter December 2013

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Regulatory Update

Data Sharing

The EMA released a [press release](#) on the 17th December 2013 noting it has reviewed all comments received on its draft policy on publication and access to clinical trial data (more than 150 individuals and organisations submitted over 1,000 comments). The Agency will continue to work with stakeholders including industry, academia and civil society organisations, to further clarify and fine-tune the proposed rules to achieve the broadest possible consensus. This work will be guided by a set of key principles agreed by the Agency's Management Board (MB) on 12 December 2013. The **key principles include**:

- a stepwise approach for implementation with, as a first step, preparation for the publication of clinical study reports redacted as appropriate;
- development of a methodology for de-identification of patients;
- definition of a standard format for the submission of data.

The principles also foresee the introduction of preliminary steps prior to data access designed to address the risk of possible unfair commercial use of data, while ensuring proactive and non-selective access ('use control' not 'access control'). The policy on publication of and access to clinical-trial data and an implementation plan will be discussed at the March 2014 Management Board meeting.

The Agency reiterates its firm commitment to pursuing the objective of full transparency regarding clinical trial data. The Agency will continue to monitor progress in the Court cases brought by two pharmaceutical companies against the Agency and the on-going discussions on the new European clinical trials legislation. It recognises the need for consistency in the general approach to access to documents by EU institutions and bodies, while recognising the specificity of documents in the possession of the EMA and the Agency's primary duty to protect and foster public health.

Comments on Guideline on Adjustment for Baseline Covariates

EFSPI submitted comments on the guideline on adjustment for baseline covariates. Thanks to all the individuals and associations who provided comments. The set of comments submitted can be accessed on the EFSPI website (www.efspi.org).

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Association of the month: BSS

The Belgian Statistical Society (BSS) was founded in 1937.

The scope of the Society is to contribute to scientific progress in statistics by promoting co-operation between Belgian statisticians and to help the general public to get better understanding of the place of statistics in the modern world. The Society has currently over 300 ordinary members and 3 honorary members. The B-Stat News, the BSS Newsletter, is published three times per year in January, April and September. Scientific meetings are organised each year: BSS annual meeting, General Assembly meeting and a few meetings organised by the biostatistical section.

The Biostatistical section of the Belgian statistical society was found in 1993, and its first task was to provide comments on the ICH E9 guideline. It was founded by statisticians working for pharmaceutical companies and was quickly opened to those working for CROs or academia. This section helps to organize the BSS annual meetings, providing invited speaker as well as reviewing contributed papers. This section has organized joint meetings with the Quetelet Society (Belgian Region of the International Biometric Society), and since 2011 with other members of the EFSPI.

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EFPIA new R&D model

The European Federation of Pharmaceutical Industries and Associations (EFPIA) published an article in [Nature](#) in 2012 that presented how R&D models could be improved and supported by appropriate regulatory pathways which would enable new drugs to be developed with greater efficiency, in a framework that is financially viable for all stakeholders. A variety of work streams have been set up within EFPIA to progress with the 7 themes noted in the paper.

One of the work streams is focussing on **new clinical trial design** based on new science (statistical methodologies, new technologies and big data/real life data) with the aim to developing the 'clinical trial of the future' which will have more predictive, less costly and shorter clinical trial programs with threefold output: (i) rationalizing the way clinical trials are done in the current regulatory framework; (ii) testing new trials design and their suitability for stratified/personalized medicine supporting the Medicines Adaptive Pathways to Patients (MAPPs); and (iii) developing new statistical methodologies and patient stratification tools through better incorporation of a variety of data sources (pre and post marketing).

Representatives from the EFSPI Statistics Leaders network attended a workshop held at the EFPIA offices in Brussels on the 11th December 2013. The workshop included a review of all existing initiatives which have elements related to clinical trial design (including those within and outside the Innovative Medicines Initiative [IMI]), case studies illustrating some of the novel ideas being investigated in a couple of the ongoing initiatives,

and a brainstorm of the roadmap for the 'clinical trial of the future'. EFSPI will remain engaged in this project as it moves forward. Further information will be posted to the EFSPI website as and when it becomes available. If anyone has any specific questions please contact Chrissie Fletcher (fletcher@amgen.com).

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[Update on the International Year of Statistics](#)

The International Year of Statistics (Statistics2013) has been a fantastic success. It has been a tremendous yearlong celebration of all things statistics. For instance, an engaged network of more than 2,300 organizations—national and international professional statistical societies, colleges and universities, primary and secondary schools, businesses, government statistical agencies, and research institutes—representing 128 countries came together to promote statistics around the world. Hundreds of informative and insightful events worldwide—many attended by the public—were sponsored by Statistics2013 participating organizations. Media organizations the world over took notice of the International Year of Statistics and shared the news with their audiences.

These and other successes are prime examples of why the organizers of Statistics2013 decided it was essential to continue beyond the end of this year the momentum generated by the global Statistics2013 movement. To continue carrying the key messages of statistics to the world's population, the Statistics2013 Steering Committee has selected a new name for the movement. That new name is: **The World of Statistics**.

The mission of The World of Statistics will be to further advance the goals of the Statistics2013 campaign. As a reminder, those objectives are:

- Increase public awareness of the power and impact of statistics on all aspects of society
- Nurture statistics as a profession, especially among young people
- Promote creativity and development in the sciences of probability and statistics

The "The World of Statistics" will come with a new website and related communications mediums.

The five statistical societies that launched the International Year of Statistics have formed an organization called the International Prize in Statistics Foundation. The foundation will provide the framework that will ultimately lead to the annual presentation of a "Nobel-like" prize in statistical science, to be called the International Prize in Statistics. The award will recognize the major achievement of an individual or team in the field of statistics.

Thanks for everyone's support in EFSPI to the International Year of Statistics, and for your continued support to spread the word on all aspects of statistics through 'The World of Statistics' efforts.

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The EFSPi Council met in Belgium on the 4th December. EFSPi have renewed their contract with KSAM who will provide Executive Office support for a further 3 years. Thanks to KSAM for all their support in 2013. Plans are progressing to update the EFSPi website, and a variety of vendors are currently being evaluated. Planning for the next EFSPi Statistics Leaders meeting in the Spring of 2014 is also underway.

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.

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Merry Christmas and Happy Holidays

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