



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

EFSPI Newsletter June 2017

In this newsletter:

[Regulatory](#) – regulatory statistics workshop

[Scientific](#) – scientific meetings, Asterix

[Country news](#) - BIAS (Italy), PSI (UK), SFdS (France), SSL (Finland)

[Other news/events](#) – IMI PREFER, EFPIA Clinical Trial Design Taskforce, JSM

[Job postings](#) – Statistical Programmers

[The World of Statistics](#)

[Follow us on Twitter and LinkedIn](#)

[And finally.....](#)

Regulatory

The 2nd **EFSPI regulatory statistics workshop** will take place on the **5th-6th October 2017** in Basal, Switzerland. This workshop will be dedicated to opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion. Click [here](#) to view the agenda and to register click [here](#). Specific focus areas include multiplicity, estimands, predictive biomarkers/companion diagnostics and early development. Development issues in a range of disease areas will be discussed in addition to a contributed short topics session. Materials from the first workshop can be found [here](#).

[back to top](#)

Scientific

On June the 23th, the joint EFSPI/PSDM meeting on “**Statistical Aspects of Safety Data in Clinical Trials**” took place at Astellas in the Netherlands. With more than 60 participants, lively presentations and interactive discussions it was a successful meeting. The slides will be shared on the EFSPI website.

The next 1-day meeting will be on **Oncology and Survival Analyses**, planned for November in Brussels, and a third joint meeting together with the PSI on **HTA** is planned for the fourth quarter of 2017. More information will follow.

(The planned meeting on [Advances in Clinical Trial Design](#) has been rescheduled to early 2018.)

Together with the SIG on Integrated Data Analyses, we are planning a webinar in the last week of September. More information will follow.

Asterix



EFSPi is one of the partners in the FP-7 projects, called Asterix, on new innovative methodology for rare diseases. This consortium is reaching its final stage, and as a result this consortium is organising the **Asterix End Symposium** on **September 18 and 19** in **Zaandam** (the Netherlands)

*** REGISTRATION IS OPEN ***

It will discuss key topics such as novel novel approaches to randomization, sequential designs, multiple endpoints, meta-analyses and Goals Attainment Scaling by using examples and explanations in common, non-technical language. Special attention is dedicated to patient involvement in general and the Patient Think Tank.

More information can be found on the Asterix website [Chrissie please add link: <http://www.asterix-fp7.eu/agenda/symposium/>]

[back to top](#)

Country News

BIAS (Italy)

The next national BIAS congress will be organized in Parma on September 28th and 29th. This edition will be focused on **“Biostatistics beyond clinical trials: epidemiology, pharmacoeconomics, personalized medicine, machine learning and other hot topics”**. The Epidemiology session will involve Italian experts from both the Academia and the Industry, and it will aim to depict how observational and real world studies can play a strategic role in the development of new drugs and their importance in the surveillance of marketed products. A panel of experts led by Eva Pagano (AOU Città della Salute e della Scienza, Torino) will talk about pharmacoeconomy and its growing importance in the decision making process of the health authorities. Presentations on machine-learning (Dario Gregori, University of Padua), personalized medicine and estimands (Mouna Akacha, Novartis Pharma AG) complete the scientific program of the Congress.

PSI (UK)

The Introduction to Industry Training Course needs you! NEXT COURSE STARTS OCTOBER 2017: £1050+VAT. This course aims to describe the drug development process from research right through to research, toxicology, data management & role of the CRO, clinical trials, product development & manufacture and marketing. Please click [here](#) for more information and to register.

We want your brains! - Volunteering opportunity to share your knowledge and experience The PSI External Affairs Committee and Cancer Research UK's (CR UK) Centre for Drug Development (CDD) are looking for individuals who would be willing to volunteer their time and knowledge for a variety of opportunities. These include:

- Being part of a team helping to create and run a 1 day workshop for CDD staff on key

- statistical considerations for early phase development oncology trials.
- Or as an individual volunteering 1 or 2 days to:
 - contribute to the review of CDD's outline and full protocol templates to refine stats and analysis sections
 - advise and input into the development of outline & full protocols for upcoming trials
 - participate as a statistical reviewer in a session of the independent CDD protocol review committee

If you are interested in finding out more about supporting CRUK in this way, please get in touch with Rebecca Sudlow (rebecca.sudlow@roche.com)

ITIT and Training Committee are seeking new members! The Introduction to Industry Training (ITIT) and Training Committee are seeking new committee members. We are looking for individuals who are enthusiastic, good organisers, eager to contribute and play a key role in the continued success of PSI training courses. The ITIT committee organise a series of six two day training courses for PSI members new to industry. The training committee organise several one and two day meetings for statisticians at all career levels. For more information please contact Alex Godwood for ITIT (godwooda@medimmune.com) or Mary Elliott for training (maelliot@amgen.com)

Pharmaceutical Statistics May/June is now available on the Wiley [website](#). This issue has five papers on a diverse range of topics including QTc prolongation, use of biomarker analysis, response adaptive designs and Bayesian sequential designs.

SFdS (France)

The **International Meeting Statistical Methods in Biopharmacy** will be held on the **14-15th September 2017** with the theme *“The future of Biostatistics in an emerging world of data sciences”*. Key themes for the meeting include: regulatory statistics and beyond, statistical inference of biostatistics of the 21st Century, successful marriage between bioinformatics and biostatistics, and recurrent event analyses. More details to register will follow in future newsletters.

SSL (Finland)

SSL elected new board in the annual Spring meeting. Riku Kivimäki from Statfinn continues as the Chair, Tuukka Pölönen (PerkinElmer) continues as Finance officer and Sofia Männikkö (4Pharma) continues as a secretary. Jari Ahvenainen from Datoil Ltd is a new board member taking care of the website and information. Teppo Huttunen (4Pharma) will serve in the board as the EFSPi correspondent.

[back to top](#)

Other news/events

A 1-hour webinar presenting the **IMI Project PREFER** (Patient Preferences in Benefit-Risk Assessments) will take place on the 12th July 2017 at 4.30pm CET / 3.30pm BST. The presentation will address the objectives of PREFER, describe patient-preference studies with an example, and describe the project and key deliverables. [Click here](#) to register for the webinar and find additional information. *Please note that registration is limited to 100 places. We would therefore encourage participants to dial-in as groups where possible.*

EFPIA Clinical Trial Design Taskforce

The EFPIA Clinical Development Expert Group (CDEG) are forming a small taskforce to map out

ongoing and planned initiatives in relation to novel and innovative trial designs. Novel trial designs has been recently identified as a priority area for future IMI initiatives as well as a key focus area for EFPIA's work in digital health. Please email Chrissie Fletcher (fletcher@amgen.com) if you would like to get involved.

The **Joint Statistics Meetings (JSM)** takes place 29th July through to 3rd August 2017 in Baltimore, USA with the theme *Statistics: Its Essential*. For more information click [here](#).

[back to top](#)

Job Postings

Opportunities exist at ICON/DOC for [Statistical Programmers](#). For all current recruitment adverts and more information on how to submit recruitment adverts, please visit the EFSPi website: [Job postings](#). If you are currently seeking to hire a statistician and wish to post a job advert, EFSPi are offering one free advert for every 3 adverts posted on the website.

[back to top](#)



The World of Statistics

The World of Statistics is comprised of 2, 194 organisations across the globe. Participating organizations in The World of Statistics include national and international professional statistical societies, colleges and universities, primary and secondary schools, businesses, government statistical agencies, and research institutes. You can view the current participant and country lists involved in the World of Statistics by going to [The World of Statistics](#) website.

[back to top](#)

Follow us on Twitter and LinkedIn

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 LinkedIn.

[back to top](#)

And finally.....

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.

For more information on how to submit recruitment adverts, please visit the EFSPI website: [Job postings](#). If you are currently seeking to hire a statistician and wish to post a job advert, EFSPI are offering one free advert for every 3 adverts posted on the website.

[back to top](#)

Chrissie Fletcher
EFSPI Communications Officer

