



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

EFSPI Newsletter January 2019

In this newsletter:

[Regulatory](#) – draft regulatory guideline under review

[Scientific](#) – 2019 meetings

[EFSPI Special Interest Group](#) – 1-day HTA SIG meeting, process for setting up a new SIG

[Country news](#) – APF (Germany), IBIG (Italy), PSI (UK)

[Job opportunities](#) – Principal and Senior Statisticians, Principal and Senior Modelling and Simulation Statisticians

[The World of Statistics](#)

[Follow us on Twitter and LinkedIn](#)

[And finally...](#)

Regulatory

Please send your comments on EMA's draft [Questions and answers on Data Monitoring Committees issues](#) to Anna Berglind (Anna.Berglind@astrazeneca.com) by 28 February 2019.

[back to top](#)

Scientific

Upcoming event: **Recent Developments in Biomarkers and Subgroups in Drug Development**

On Wednesday March 20, the scientific meeting on “*Recent Developments in Biomarkers and Subgroups in Drug Development*” will take place at Astra Zeneca in Gothenburg, Sweden. This is the first joint meeting with the Swedish Society for Medical Statistics (FMS). In this meeting, experts from industry, academia and regulatory agencies will come together to share recent insights and discuss statistical challenges related to biomarkers and subgroups, with a focus on practical applications.

We will also have a [poster session](#): If you wish to present a poster, please send an abstract to Mattis Gottlow (Mattis.Gottlow@astrazeneca.com) before February 28. More information can be found on the [flyer](#), which is available on our website. and the [registration](#) is open with an early bird rate up to February 20th.

In addition, the Scientific Committee is planning for two additional 1-day scientific meetings. One

before summer, and one after the summer holidays. The one before summer will be organized jointly with the BBS in Basel on the topics of Personalised and Precision Medicine. More information will follow in the coming newsletters.

On December 12, EFSPi held a scientific meeting on Decision making in Clinical Development at Servier near Paris. The slides of the presentations of this successful event are available on our [website](#).

[back to top](#)

EFSPi SIGs

HTA 1-day Meeting

A 1-day HTA meeting will take place on **Friday 15th February 2019** hosted by **MSD in Berlin, Germany**. This 1-day scientific meeting organised by the EFSPi/PSI HTA SIG will provide an update on latest trends in HTA in Europe. HTA research methods will provide insights on topics such as meta-analyses and evidence synthesis with few studies, estimands in oncology, analysing adverse events with varying follow-up times, handling missing data in real world data, and subgroup analyses. Industry HTA case studies will also be presented. To view the flyer click [here](#) and to register for this event visit the [EFSPi website](#).

Setting up a new SIG

Special Interest Groups are important to EFSPi as they allow a dedicated group of experts and individuals to collaborate and discuss across a range of stakeholders and organisations a specific area or key topic of interest. If anyone is interested in setting up a new SIG, please click [here](#) to see a summary of the existing SIGs and to access slides describing how to set up a new SIG.

For further information on existing SIGs please contact Anne Danniau (Anne.Danniau@grunenthal.com) or Maylis Coste (maylis.coste@servier.com) who oversee the SIGs for EFSPi.

[back to top](#)

Country News

APF (Germany)

The next APF Statistical Leaders meeting will take place 11.04.2019 at Boehringer Ingelheim in Ingelheim.

IBIG (Italy)

On the 22 February 2019 the 6th Italian CDISC User Group Network Annual Meeting will take place in Milan at The SAS Institute. The event is free, maximum 80 seats. This is a collaboration between IBIG, SAS, CDISC and Cytel. Further information can be found at <http://www.biostatistici.it/news-eventi/>.

On the 22 March 2019 a course of Statistics in Oncology for non-statisticians will be held in Milan.

In mid-April (date TBC) a one-day seminar on Adaptive trials in Oncology will be held, further details

will follow.

On the 10 May the 1st Italian Bayesian Day (for Clinical Research) will take place in Turin. This event is being hosted by IBIG in collaboration with Politecnico Turin. More details and agenda in the coming weeks.

PSI (UK)

2019 PSI CONFERENCE: 2 - 5 June, London Data Driven Decision Making in Medical Research

Don't forget the poster deadline for this years conference is **Thursday 28th February**. We accept abstract on any topic you feel is relevant to Statisticians working in the pharmaceutical industry. If you're looking for some help on what to submit, click [here](#) to see a list of topics and to download the abstract template

The scientific programme is now available to view online. Please note that the content is fixed but minor changes may occur to the session names and timings. Have a [look](#) at what we think will be some fantastic content for the conference.

Act now to join us in London this year. [Click here to register](#) to receive the early bird fee up to the 20th March 2019! To view all the latest information on the Conference, please visit the [PSI website](#).



Visit the Video-on-Demand Platform here!



FEATURED VIDEO: PSI Webinar: Avoiding Pitfalls in Supervised / Unsupervised Learning

Alexander Schacht, Andy Nicholls, Ilya Lipkovich, Jennifer Gilbride -

As the availability of big data increases and statisticians assist with predicting outcomes or understanding patterns in an ever-wider variety of scenarios then supervised and unsupervised learning methods become increasingly called upon. Such machine learning algorithms offer the opportunity to understand potential predictors or clusters amongst large datasets but are also subject to the risks of overfitting or over-interpretation. The webinar video introduces ideas and shares experiences in this field. The talks introduce several supervised and unsupervised learning methods and cover data-driven subgroup identification in clinical trials, and case studies of implementation clustering algorithms.

EFFECTIVE STATISTICIAN

Calling for Statistical Leadership

In January, we dive deep into the topic of statistical leadership. In 3 episodes with Gary Sullivan, we talk about:

- What this is
- Examples of how it shows up
- Skills you need to develop
- What you can practically do to improve your leadership skills

Check out the last 3 episodes of The Effective Statistician Podcast here:

1. [Understanding leadership deeply – trust, relationship, and influence for statisticians](#)
2. [Skills you need to become a better leader!](#)
3. [Practical steps to improve your leadership skills](#)

You can listen to the podcast on the homepage but also on your “podcast” app on your iPhone. If you own an android, you may use an app like Stitcher. Just search for “the effective statistician” in your app. Finally, you can also find it on Spotify.

Toxicology Special Interest Group Free Webinars

The Toxicology Special Interest Group holds quarterly free webinars. Our upcoming webinars are on the following topics:

Tuesday 19th February 2019 - Professor Malcolm Macleod on Data Quality and Pre-Clinical Research

Tuesday 16th April 2019 - TBC

Tuesday 18th June 2019 - TBC

All take place at 14:00 UK time. Full details will be released closer to each webinar, or contact Gareth Thomas (gareth.thomas@envigo.com) to be kept up to date on all ToxSIG activities.

[back to top](#)

Job Opportunities

Opportunities exist for [Principal and Senior Statisticians, and Principal and Senior Modelling and Simulation Statisticians.](#)

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 2,360 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](#)

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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.....

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[back to top](#)

Chrissie Fletcher
EFSPi Communications Officer

