



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

EFSPI Newsletter January 2020

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EFSPI Council News

EFSPI had a busy 2019 and successful year with a lot of scientific discussions and activities. We had three successful scientific meetings and the 4th EFSPI regulatory statistics workshop in Basel. All of these events have been well attended, especially the regulatory workshop which again set or confirmed a very high standard.

We made great progress on the organization of SIGs. Not only that we have seen some new SIGs starting 2019 we also reached a strategically important agreement with PSI on how we organize SIGs in Europe. In the future, we will stop talking about PSI or EFSPI or joined SIGs which was often confusing in the past. Instead, we will recognize more the region we are working in and call them European SIGs (ESIGs). These SIGs will be jointly sponsored by EFSPI and PSI. A small oversight committee will be formed to which PSI and EFSPI will send each one representative. For EFSPI this is now Gaelle Saint Hillary and for PSI Adam Crisp.

Finally, my two year tenure as EFPI president ended as well with the end of 2019 and it is my great pleasure to introduce to you the new EFSPI president, Stefan Driessen, from the Dutch organization. I hope 2020 will be equally inspiring and successful as 2019 was.



Dear fellow statisticians

Let me start with wishing you all the best for 2020, and may you thrive both personally and business-wise and stay in control in these dynamic times. And let me also right away thank Uli Burger for being our President for the last two years. He did an outstanding job in my view and I have to say it is really an honour for me to succeed Uli as the Chair of EFSPi for the coming two years. I like working for EFSPi and hope to serve you all well.

Why?

Well, EFSPi is a very important organization for statisticians working in the pharmaceutical industry in Europe. EFSPi aims to help each of you to keep up to date with the advancements in the professional standards of statistics. It does so by organizing scientific meetings and the yearly regulatory workshop (that in 2020 will have its first 5th years jubilee!). Importantly EFSPi wants to promote the standing of the statistical profession in the industry, and support you in your career with attention to capabilities other than technical matters, like influencing skills. Further EFSPi aims to facilitate networking and act as a platform to bring together statisticians from different countries and companies to learn from each other and support each other. The strategy to realize all this is very much fueled by the yearly Statistical Leaders Meeting that had its 10th year anniversary in 2019. The advice and feedback from Statistical Leaders is a great help to EFSPi so we can understand the latest developments in the evolving areas of data science and statistics, and promote the value and role of statisticians.

What can we expect the coming years?

With Brexit underway, we hope that as a statistically community we will stick together in EFSPi and keep the many good things we have realized over nearly 30 years. Industry is undergoing a digital transformation and the huge increase in availability of data that will require statisticians to seize opportunities to broaden our scope and augment our capabilities while maintaining the statistical rigor as needed. With increasing access to data there will be increasing use of statistics, but what will this mean to the statistician in Pharma? It will be important for me and EFSPi to work on these matters and help support you as much as possible.

For you and with you

EFSPi wants to do all of this for you, but can also not do without you. Your support is very much desired and needed. Be it in your national organizations or in EFSPi, you are part of shaping the future; for yourselves, for us, for all of us together. Luckily, we have so many excellent and experienced statisticians in the EFSPi Council and in all the national associations, and I am sure working together we will make a big difference, and support all of the activities noted above in the best way possible.

Upwards and Onwards for EFSPi, as they say, and let the future be bright for statisticians in Europe's Pharmaceutical Industry!

Stefan Driessen

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Regulatory

FDA published a draft guidance on the revision of its guidance on “Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products” (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-evidence-effectiveness-human-drug-and-biological-products>) please send your comments to Tony Sabin antony.sabin@astrazeneca.com and Christoph Gerlinger christoph.gerlinger@bayer.com by February 14th the latest as the final comments are due already February 18th.

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Scientific

The Scientific Committee is planning for a number of events in 2020. Although none of them have a confirmed date, these are our intended meeting in preparation for 2020:

- A one-day meeting on **Soft skills of a statistician** , with a planned date in the end of the first quarter, beginning of the second quarter. Rather than a course, the focus will be more on an overview of skills needed to be impactful, and the link to communication and the core of our profession.
- A joint EFSPi/BBS meeting on **Health technology Assessment**, looking back at ‘10 years of HTA’ and looking forward. This 1-day meeting will take place in Basel, June 30 (to be confirmed).
- A joint BBS/EFSPi/PSI seminar will be organized together with the European SIG “**Estimands in Oncology**” on this topic in Basel around mid-2020.
- A meeting on **Vaccines**, jointly organized with the Belgian Association (SBS/BVS) and the SIG on Vaccines. The aim is to have a combination of a course and a scientific meeting, which will take place in October near Brussels.
- A meeting together with the SIG on **Small Populations** in the second half of 2020

As soon as we have more concrete information, we will share with you via the Newsletter and our website.

ESIG News

Health Technology Assessment (HTA)

The HTA ESIG have set their goals for 2020 with priority areas of focus including: national HTA agency hot topics, evidence synthesis including generalisability of clinical trial and real world evidence, patient perspectives in HTA, and estimands in HTA.

The HTA ESIG is celebrating their 10-year anniversary. Set up in January 2010, many of the founding members of the HTA ESIG continue to be actively engaged today, their passion is inspiring and motivating. And many new members have joined and also making important contributions to HTA analytics.

The HTA ESIG will be celebrating their 10th birthday at the EFSPi/BBS HTA 1-day meeting being planned for the 30th June in Basel. More details will follow but hold this date and join us to hear about the great progress made to date, and what are the key challenges in HTA in the future.

Anyone wishing to know more about the HTA ESIG please contact Chrissie Fletcher (chrissie.a.fletcher@gsk.com) or view the HTA ESIG materials on the PSI website (<https://www.psiweb.org/sigs-special-interest-groups/hta>).

Data Transparency

The data transparency ESIG met on the 21st January 2020 to agree the objectives and key goals for 2020. The objectives agreed include:

1. Improve understanding, implementation and examples of anonymisation methodologies within the context of clinical trial data sharing.
2. Promote an understanding of the challenges and responsibility statisticians have when re-using or sharing clinical data.
3. Influence and shape the environment and policies regarding clinical data sharing.
4. Collaborate with other groups and stakeholders within this area.

The ESIG is proud to be leading a parallel session at the PSI Conference which will be in memory of Sally Hollis. Sally was a founding co-chair of the ESIG and she had a significant impact on shaping and influencing the field of data transparency.

For more information about the ESIG please contact Rebecca Sudlow, Chair (rebecca.sudlow@roche.com) or visit the PSI website: <https://www.psiweb.org/sigs-special-interest-groups/data-sharing-working-group>.

Country News

AFP (Germany)

APF held the German statistical leaders meeting and the annual fall workshop on Real World Evidence end of November in Ludwigshafen. On March 16th, 2020 APF is co-organizing a workshop on 'Analysis of adverse events in the context of estimands' in Heidelberg. The program can be found here: <https://www.klinikum.uni-heidelberg.de/medizinische-biometrie/veranstaltungen/workshop-16-maerz-2020>.

IBIG (Italy)

IBIG Under 35 recently created. Members are:

- Luca Grassano, GSK Vaccines
- Daniele Bottigliengo, University of Padua
- Andrea Nizzardo, Menarini Ricerche
- Veronica Sciannameo, University of Padua

IBIG in collaboration with Politecnico of Turin will organize a Course on "Early phase clinical trials". Prof. Thomas Jaki and Dr.Pavel Mozgunov from Lancaster University will hold the course that will take place from 6th to 8th May 2020 in Turin. More details at www.biostatistici.it

PSI (UK)

2020 PSI Conference



The conference theme for 2020 is "Shaping the Future of Statistics" and will take place in Barcelona on 7th-10th June 2020. To register to attend the 2020 PSI Conference in Barcelona and book your pre-conference course place, please [click here](#). To find out more information about the Conference - such as the venue, pre-conference course information, or sponsorship, [please visit the PSI website](#). Don't forget that the poster deadline is **Friday 28th February**. Click [here](#) to see a list of topics and to download the abstract template.

A PSI Training Course - Practical Approaches to Designing Adaptive Clinical Trials Wednesday 12 - Thursday 13 February 2020, London. This hands-on course will provide a deep dive into 4 software packages used to design adaptive clinical trials. The course will start by providing a general overview of adaptive designs, explaining the different type of adaptations possible and the benefits of each design. Following this, participants will be given the opportunity to have a go at designing trials in R (using RPACTS), EAST, FACTS, and nQuery. Click [here](#) to register.

A PSI Training Course - Bayesian Practical Course using R and SAS Tuesday 18 - Wednesday 19 February 2020, Heathrow, London. This practical training course will give a deep dive into performing Bayesian analyses in R and SAS. It is aimed at statisticians who need to be able to conduct Bayesian analyses as part of their day to day work. By the end of the course participants will be able to conduct their own analyses. Click [here](#) to register.

Would you be interested in working with the PSI ToxSIG Committee?

As a group of Statisticians working within Toxicology, but covering wider pre-clinical/non-clinical areas, the PSI ToxSIG committee hold regular TCs, organise up to 4 free webinars per year and run an annual 2 day workshop. Being a committee member does not take up significant time but has presented a number of advantages to both past and present committee members. The committee are currently looking for more companies to be represented on the committee. We currently have representatives from Boehringer Ingelheim, Covance, Janssen (JnJ) and GlaxoSmithKline. If you work within a related pre-clinical area and would like to be involved in this wider support network, please get in touch.

Members of the PSI Toxicology Special Interest Group committee have found this to benefit them in the following ways:

- Helps to forge partnerships with statisticians across the industry with a common goal
- Engage with some of the experts in this field
- Opportunities to be involved in writing or contributing to published papers
- Identifies who to contact when asked about an out-sourced study
- Learning on a regular basis about the work being performed in other companies
- Improving personal influencing, communication and organisational skills
- Influencing the choice of webinar topics to broaden own learning
- Promoting and increasing exposure for own Company and the innovative work performed in related areas

For more information and to express an interest in joining the committee, please email gareth.thomas@covance.com.

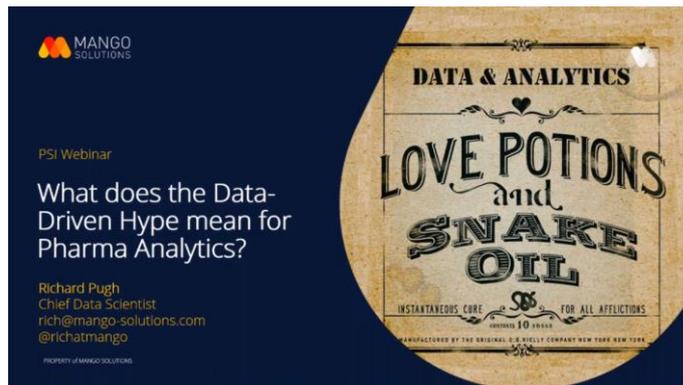
PSI New Starters Half-Day Networking Event



Thursday 6 February 2020 13:30 - 17:30 GMT

Location: King's College London, Waterloo Campus

An opportunity to meet statisticians from across the pharmaceutical industry in a relaxed and informal setting. An exciting program of events and a chance to work in small groups on a data analysis challenge. Lunch provided. Click [here](#) to register.



[PSI ToxSIG Webinar: Big Data, Data Science, AI & other Buzzwords](#)

Richard Pugh

The last 15 years has seen a massive shift in the role of data and analytics, driven by the increased hype around big data, data science, machine learning and AI. This presents both challenges and opportunities for analytic teams. This webinar will strip back the hype to look at what these buzzwords really mean, and talk about the impact this is having on the role, remit and operating model of analytic teams in the life sciences industry.

[Click here to watch](#)



[Helping statisticians having a bigger role](#)

Interview with Andy Grieve

Did you have a moment in your career, where you thought you as a statistician felt

being put in a box or labelled in such a way that limits your influence? Today's interview is surely beneficial to every statistician – both early and later in their career as [Andy Grieve](#) shares from his wealth of experience across the industry and academia working in senior roles.

[6 Effective leadership behaviours for statisticians](#)

One of my favourite leadership podcasts run by Olaf Kapinski – unfortunately in German – had a great episode recently, [click here for Leben-Führen's podcast](#). Today, we're reflecting on the 5 behaviours Olaf mentioned and add a great 6th one, which is very relevant as well.

Listen to these podcast episodes now and share it with others who might learn from it. Ciao and be an effective statistician!
Alexander Schacht

10% discount on the early bird rate available for the following courses:



Register your interest now to receive updates, hear when registration opens and receive a discount on the early bird rate (where applicable)!

Future Events

- Training Course: PK Methods and Regulatory Considerations
- Training Course: R for SAS user
- PSI One Day Meeting: Missing Data
- PSI Scientific Committee One Day Meeting: Non-proportional hazards and applications in immuno-oncology

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Volunteers needed

EFSPI are seeking volunteers to join an EFSPI Communications committee. If you have expertise in using a variety of communication channels and you have ideas and suggestions for how EFSPI could

improve the website and its use of social media, please contact Chrissie Fletcher (chrissie.a.fletcher@gsk.com).

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Job Opportunities

For 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.

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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.

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And finally.....

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Chrissie Fletcher
EFSPI Communications Officer

