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

EFSPI Newsletter February 2019

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EFSPI Chair

2018 was a very busy year, probably for every one of us, for me personally, but also for EFSPI as an organization. It was the first year of my two-year tenure as president, a lot of activities were ongoing in 2018 and some of them were really important for the organization.

As every year we organized a number of seminars and workshops to support scientific discussions in our communities. 2018 we had a workshop in March on Recent Advances in Clinical Trials jointly with the PSDM hosted by Astellas in Leiden, we had a workshop on Small Populations together with the BBS in Basel in June, hosted by Idorsia, and finally as a last event we had a workshop on Decision Making in Drug Development in December, hosted by Servier in Suresnes. And finally, we were able to hold the third annual EFSPI regulatory statistics workshop in Basel. Especially the annual regulatory statistics workshop is really important specifically for us as it brings EU regulators and

industry together to discuss important topics relevant for both sites. Importantly, the workshop is organized by a joint committee from both sites, EU regulators and industry representatives to ensure that important topics from both sides are discussed in the workshop. Of note, this year also Rajeshwari Sridhara from FDA joined the conference. It takes a lot of energy to organize such a workshop, from everyone in the scientific committee and the local organization committee and especially from the chair person. This year the chairperson role was very successfully taken up by Kaspar Rufibach. Many thanks to Kaspar and everyone on the scientific organizing and the local organizing committees for this event! And many thanks to Egbert Biesheuvel for organizing and aligning all these seminar and workshop activities.

We had this year also the 9th statistics leaders meeting hosted by Arlenda at Louvain-la-Neuve on July 12th. We brought again about 30 industry leaders together to discuss important topics. More information can be found on the EFSPI web. After the first 8 statistics leader's meetings have been organized by Stefan Driessen this was the first one organized by Justine Rochon. It was great to see that because of a great handover we were able to maintain continuity of this meeting on one hand whilst being able to bring new elements in on the other hand. Many thanks to Justine and Stefan for another very successful meeting and a very successful handover!

Another important scientific element of EFSPI are the SIGs, i.e. the scientific interest groups, in which everyone across Europe can get engaged in an important topic. We share most of the SIGs together with PSI which makes a lot of sense for attracting as many colleagues as possible. Also, for the SIGs we had a successful handover this year from Stefan Driessen to Maylis Coste and Anne Danniau. Thanks again to Stefan for all his work on this beforehand and to Maylis and Anne to take on this important activity. Of note, this year we also saw three new SIGs getting approved, one on the use of historic control data and two on the use of estimands in Neuroscience and Oncology.

There were also a lot of important "administrative" activities this year to finish. Most importantly, we became a registered association in Denmark. This is very important for us as an organization as it allows us to officially participate in EU projects. The registration was not straightforward as we are not a usual association of members but of member organizations only. Originally, we thought to register in UK, but Brexit really interfered with that as we wanted to be an EU registered organization. After a lot of discussions, we found out that Denmark would be the best country for registration. Denmark however demanded to define a local role of a director in Denmark to cope with the Danish law; I am happy to report that Mette Krog Josiassen accepted this role. Many thanks to her! As a consequence, we also had to adopt the constitution of EFSPI. An update can be found on the EFSPI webpage. Finally, as a registered organization we were also affected by the new EU's General Data Protection Regulation (GDPR); and we needed to define a new corresponding policy which is now also available on the EFSPI webpage. Many thanks to everyone involved in these really important activities!

Finally, running successfully an organization like EFSPI goes much beyond the capacity of one individual. I am very fortunate to have a very active EFSPI council beside me and I am grateful for all the help I have received from my colleagues on the council and would like to thank every council member for all the support. Specially, I would like to thank Marisa Bacchi as vice president, Birgitte Biilmann-Roenn as treasurer and Christoph Gerlinger, Egbert Biesheuvel and Chrissie Fletcher for their countless activities.

We are now looking forward to 2019 to be another successful year for EFSPI. We have already started to organize this year's scientific meetings, especially the next EFSPI regulatory statistics workshop. It will take place on September 23/24th 2019, one more time in Basel. For 2020 it is planned to move it to Amsterdam area 2020 to be closer to the EMA. I am very confident that we

will have this year again an attractive program leading to great discussions! And it would be great to see again a lot of colleagues from all over Europe to join the meeting!

We will continue to keep you informed about all the news in our monthly EFSPI newsletters.

Uli Burger, EFSPI president

Regulatory

EMA has started their relocation to Amsterdam which is to be completed by March 4th. See https://www.ema.europa.eu/en/about-us/contact/how-find-us for more information.

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. More information can be found on the flyer, which is available on our website and the registration is open.

EFSPI and BBS will organize a joint one-day meeting on **Precision Medicine**. The meeting will be held on **Tuesday June 4** and will be hosted by Actelion in Allschwil (near Basel). Confirmed speakers, thus far, include Stephen Senn, Niko Beerenwinkel (ETH Zurich), Tomasz Burzykowski (IDDI) and John Doyle (IQVIA). Registration will be opened beginning of March on www.efspi.org.

In addition, the Scientific Committee is planning for a third 1-day scientific meetings after the summer holidays. More information will follow in the coming newsletters.

Country News

APF (Germany)

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

BBS (Switzerland)

BBS Spring Seminar: Synthetic controls – what do we need and how far can we go? May 10, 2019 from 9:00-16:30, Roche Auditorium, Viaduktstrasse, Basel. Sessions include: an overview of the use

of synthetic controls, case study examples, views from regulatory, HTA and academia, and a panel discussion.

The Seminar is this year free of charge. For organizational reasons please register by sending an email in advance to fred.sorenson@xcenda.com. Registration will close by Friday, April 26, 2019

IBIG (Italy)

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
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 increasing 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

Communication and Data Science -
2 interesting interviews

What you can learn about communication of statistics from a statistician working for the BBC

It's surely not the norm, that a statistician from the pharma sector ends up working for BBC. But Robert Cuffe has taken this step and needs to explain statistics to non-statisticians on a daily basis.   In this episode, he shares the different methods he's using. We also dive into common pitfalls that we as statisticians trap into. Finally, we also learn how we can improve our publications to make sure that the science is reported correctly in the broader news. Listen to the episode here!

Current trends in data science for pharma – findings from a qualitative survey and what we should do about it!

Do you want to learn where the health sector might be heading in terms of data science? Do you understand the opportunities and barriers in terms of the application of data science? Are you prepared to learn the individual skills needed for these changes? Then this interview with Ursula from Cytel provides you with the relevant answers! 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 PSI Special Interest Group "Toxicology" have a series of regular FREE webinars dealing with statistical topics faced in toxicology and related fields. The presentations will run for an hour, with approximately 45 min presentation and a Q&A session in the remaining time.

The webinars planned for 2019 are:

- Tuesday 16th April 2019 - ICH S1 revision and CAD Process

- 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.

PSI Webinar: Statistical Engagement with Commercial Activities

Tuesday 12th March 2019 13:00 - 14:30 UK Time
Presenters: Camilo Zapata (Alkermes), Helena Baptista (Lily), Lucy Frith (GSK)

An interesting webinar with three speakers looking at how pharmaceutical statisticians can

engage with their commercial and other business teams. Camilo Zapata will introduce the field of "business analytics" in the context of pharmaceuticals, Helena Baptista will talk about how we can measure the effectiveness of our communications and Lucy Frith will speak about communicating efficacy data in a manner appropriate for health care professionals. For further information on the webinar, please click here.

Network Meta Analysis (NMA) for Statisticians

7th - 8th March 2019, Crowne Plaza, Heathrow
Presenter: Georgia Salanti (ISPM, Bern)

Are you a statistician, epidemiologist or other quantitatively-minded researcher who is involved or may be involved in the future in the preparation of HTA submissions? PSI are running a two-day training course on Network Meta Analysis for statisticians. This intensive course will cover all basic and advanced aspects of synthesis of evidence from studies comparing competing treatments for the same health condition. By the end of this course participants will have an understanding of the role and potential of network meta-analysis, the principles, steps and statistical methods involved; the biases that can distort indirect comparisons and network meta-analysis. The course will consist of lectures, practical examples and discussions. Participants will gain practical experience in performing analyses in R software and the freely available web application CINeMA.   For more information click here.

PSI One Day Meeting: New Starters SIG

Date: 28th March 2019
Location: IQVIA, 500 Brook Drive, Reading, RG2 6UU

This is the inaugural meeting of the recently relaunched New Starters Special Interest Group. The aim of this meeting is to provide a relaxed environment for early career statisticians to network and interact with their peers across the industry. We will provide a program of informal talks alongside breakout and ice-breaker sessions in order to facilitate discussion amongst attendees. For this one-day meeting the audience will be peers with similar levels of experience and sessions will include content of interest to statisticians early in their careers. In addition to presentations from fellow statisticians there will be a workshop on estimands and ample opportunity to connect with colleagues across the industry.

If you're interested in presenting at this event, please send a brief description of your proposed presentation to Sam Hadlington by 22nd February 2019. We're compiling a New Starters email distribution list so that we can let members know about future events and ideas for New Starters. Please click here to join the mailing list.

PSI Toxicology SIG Workshop 2019

2nd - 3rd April 2019, Crowne Plaza, London Heathrow

The Toxicology SIG provides a forum for statisticians working in regulatory and investigative toxicology to discuss issues and interact with one another.

This 1.5-day workshop will involve approximately 20 statisticians, focusing on discussions around "best practice" in the statistical analysis of various data types.

The topics selected for the agenda include:
- Bayesian approaches in pre-clinical
- Brainstorming to prepare a paper on statistical approaches in Toxicology/Safety Assessment studies
- Translation between pre-clinical and clinical
- Exploration of new areas where we can have an impact (eg Data Sciences, Big Data, Machine Learning…)

All this, including overnight accommodation for one night, dinner, breakfast and refreshments during the 2 days, is available for £205 per delegate. Registration is open here and spaces are limited.

Estimands and Sensitivity Analysis in Clinical Trials

22nd - 23rd May 2019, Crowne Plaza, London Heathrow
Presenters: Christine Fletcher, Frank Petavy, Frank Bretz and Rob Hemmings

This two-day training course on Estimands will cover the following topics:

- Estimand Framework
- Description, strategies, and construction of estimands
- Impact on trial design, conduct, analysis and documentation
- Estimand case studies

SSL (Finland)

SSL organized a webinar on January 23rd. The topics/talks were:

- Love of Errors- When Speed Matters -- Adam Amborski (Statfinn)
- StanCon 2018 -- Mikko Marttila (Orionpharma)
- Data Transparency -- Jari Ahvenainen (Aastat)

The webinar was participated by approximately 25 SSL members and received a good coverage.

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.

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.

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.

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.

Chrissie Fletcher
EFSPI Communications Officer