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

EFSPI Newsletter September 2021

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EFSPI Regulatory Statistics Workshop 2021

On 13-15th September the 6th EFSPI Regulatory Statistics Workshop took place virtually as three half-day webinars. With a record number of 1271 registrations interest in the event was great and again massively growing compared to last year. A record number of 71 colleagues from regulatory agencies registered as well as. See here for an analysis of registrations. A few highlights from the organizer's perspective were:

- With 42% registrations of non-statisticians we continue to reach a broader audience.
- We had registrations from 42 countries globally, see above link for details.
- Attendance of industry, academic, and regulatory colleagues, with engaged discussion on a broad range of topics relevant to contemporary drug development.

We were very excited to have talks from high-profile speakers from
- Five regulatory agencies (European Medicines Agency, Medicines and Healthcare products Regulatory Agency, Norwegian Medicines Agency, FDA, and Japan PMDA),
- Three universities (Universitair Medisch Centrum Utrecht, Radboudumc, University of Birmingham), and
- Eight pharma companies or CROs (Bayer, Scott Berry Consultants, elderbrook solutions GmbH, GSK, IQVIA, Lundbeck, Novartis, Roche).
- Regulatory speakers were Peter Arlett, Ralf Herold, Mark Levenson, Anja Schiel, Armin Koch, Kirsty Wydenbach, Chantal Quinten, Khadija Rantell, Tim Williams, Yuki Ando.

An asset of the workshop is how approachable regulators are, even in this virtual format. And they do not shy away from pronounced statements, in their talks and in panel discussions. The program, all but one slide deck and recordings of the first two days are available on the EFSPI webpage here.

We thank the Scientific Committee, all speakers, chairs, panelists, and anyone else who contributed to make this workshop a success for their work!

The local organizing committee Egbert Biesheuvel, Hans Ulrich Burger, Christoph Gerlinger, Kaspar Rufibach, Emmanuel Zuber

Scientific

There is an upcoming **free** webinar on **Friday October 8** on *Let's talk about Career Development.*

Traditionally, statisticians think of our career paths as being more or less linear. Taking more senior roles and move from one company to another, but it is common for us to take on a similar role to the one we had before. We have organised a conservation with *Karen Facey* and *David Wright* to give you a different perspective on career development. Whether your career is going just fine, or whether you think you could do with some food for thought for your next development plan discussion – join us and listen to some inspiring reflections on career development. More information can be found on the website and registration will open soon.

Egbert Biesheuvel, EFSPI Scientific Committee Chair

ESIG of the Month: Regulatory

The Regulatory European Special Interest Group (ESIG) is probably the longest serving ESIG, although it was predominantly referred to as a committee until the end of 2020. We have a total of 20 members from 8 countries and 17 companies, and our purpose is to co-ordinate regulatory activities across the European Pharmaceutical Statistical community and to engage with European Regulatory statisticians (here is the link to our page). It is probably fair to say that the COVID-19 pandemic has stretched out colleagues in Regulatory Agencies, and as a result we have seen fewer regulatory guidelines being issued (as either draft or final). This has not reduced our activities, though, and here are some key ones coming up:

Jointly with the Biopharmaceutical Section of the American Statistical Association (ASA) we are jointly organising a webinar on Complex Innovative Designs (CID) in practice. This will be held on 21 October (14.00 – 16.00 BST), with speakers from the FDA, Novartis and GSK. If you are interested, then please find further information and a link to the registration page here.

We typically meet annually with both the MHRA statisticians and the EMA Biostatistics Working Party for an exchange of statistical topics important for both regulators and industry. The EMA has scheduled this again for 29 October and asked us and other statistical stakeholder organisations for topics. The proposed topics for the event this year are 1) Use of external control data and

2) Raw data submission. EFSPI is invited to present on topic 2 together with EFPIA. If you would like to contribute please contact Christoph Gerlinger (christoph.gerlinger@bayer.com) or Jürgen Hummel (Jurgen.Hummel@ppdi.com).

Several of our members were on the scientific and organisational committee for the 6th EFSPI Regulatory Statistics Workshop held online between 13 and 15 September, covering decentralised trials, complex innovative designs and real-world data. We hope many of you were amongst the >1000 registered attendees and enjoyed the event.

The ESIG have recently provided high-level comments on the Good Clinical Trials Collaborative (GCTC)'s draft Guidance for Good Randomized Clinical Trials. Key comments focussed on the absence of any reference to estimands and insufficient discussion on non-inferiority vs. superiority trials. Three recent Chinese guidelines were also reviewed but there were no major comments.

*** Reminder *** Accelerating Complex Clinical Trials in Europe and beyond workshop*

A multi-stakeholder workshop to develop shared solutions for the use of complex clinical trials to optimise drug development in Europe. **5 October 2021, 14:00 - 19:00 CET and 6 October 2021, 14:00 - 18:30 CET**

Complex Clinical Trials (CCTs) have the potential to accelerate drug development and enable patients to get timely access to transformative therapies. The main objective of this workshop is to develop shared solutions addressing key challenges with CCTs, discuss global implications of CCTs, identify emerging best practices to facilitate the use and acceptance of CCTs to multiple stakeholders, and identify synergies with existing initiatives such as IMI EU-PEARL and CTTI. The workshop will include a mix of plenary and break-out sessions involving representatives from Industry, regulatory agencies, HTA agencies, academia, patient advocacy and ethics committees. Click here to see more details and to register.

Chrissie Fletcher on behalf of the EFPIA Complex Clinical Trials Team

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Christoph Gerlinger   **and** *Jurgen Hummel*
(EFSPI Regulatory Chair)   *(PSI Regulatory Chair)*

Please look out for updates and other ESIG news at https://www.psiweb.org/sigs-special-interest-groups/sigs

Adam Crisp (PSI SIG liaison)   *and Gaëlle Saint-Hilary (EFSPI SIG liaison)*

Country News

APF (Germany)

The annual virtual autumn workshop will take place on Black Friday Nov 26th .

FMS (Sweden)

An online autumn meeting will take place on Friday Nov 12, 9.00-12.10 CET with the theme "Collaboration between statisticians and medical scientists, perspectives on methodology, commitment and organization. "

PSI (UK)

Upcoming Events
21st October 12-1pm GMT: **PSI Careers - Lunch & Learn: Imposter Syndrome Session**
Who is this event intended for? For anyone looking to learn more about Imposter Syndrome.

What is the benefit of attending? Learn from others who relate with Imposter Syndrome; hear their experiences and advice to overcome it.

Starting 1st November 9:45am-12pm: **PSI Training Course: R for Clinical Trial Statisticians**
Who is this event intended for? Clinical trial statisticians experienced with other software languages (such as SAS) and would like to increase their proficiency in R. The content can also be applied more widely in a non-clinical trial context.

What is the benefit of attending? Attendees will learn how to understand data manipulation in R; produce R graphics with ggplot2; and perform & interpret statistical analyses in R.

2nd March 2022: **PSI Medical Statistics Careers Event**
Who is this event intended for? Students with an interest in Medical Statistics. Exhibitors from Medical Statistics fields: pharmaceutical companies, CROs, CTUs and other organisations, including universities running MSc or PhD in Statistics, or with statistical consulting groups.

What is the benefit of attending? For university students, this a chance to learn about medical statistic opportunities, network with potential employers as well as discuss recruitment possibilities. For exhibitors, this is a chance promote working in the medical statistics to students as well as further promotion of their company and any plans for student recruitment they have.

Podcasts & Webinars

PSI VisSIG Wonderful Wednesday 19: Continuous Glucose Monitoring data example
The Wonderful Wednesday of September is about the display of treatment differences in time-series data on the example of Continuous Glucose Monitoring (CGM) data. Zachary Skrivanek presents the visualisations proposed for this challenger ranging from explanatory plots with condensed information to an exploratory interactive dashboard. All visualisations are available on the Wonderful Wednesday blog.

PSI VisSIG Wonderful Wednesday 18: COVID-19 data example
For this edition of the Wonderful Wednesdays, the audience was asked to send examples of visualizations representing coronavirus data. Mark Baillie guided the webinar, showcasing different types of visualizations, such as area graphs, forest plots, streamgraphs, or network analysis. All visualizations are available on the Wonderful Wednesday blog.

The Effective Statistician

Dark Data: Why what you don't know matters
We focus on how you can grow in your effectiveness as scientists and leaders. With that in mind, we dive into this concept of Dark Data and how, where, when, why this impacts decision making in the pharmaceutical industry.

What we can learn from journalism
We talk about data visualization in journalism with Irene dela Torre Arena. She has worked for BBC so she has a background with journalism so join us and learn from her perspective.

How to ask for more money or for a promotion
The right approach to this depends on a number of things. In this episode, I share with you my learnings on how to ask for more money or for a promotion.

Alexander Schacht

Non-PSI Event

PHUSE EU Connect
Date: Monday 15th - Friday 19th November 2021 | **Location**: Virtual

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Job Opportunities

Opportunity for Global Director Biostatistics and Senior Manager, Biostatistics.

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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And finally.....

Join EFSPI on LinkedIn by searching 'EFSPI'.

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 Newsletters

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