



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

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## EFSPI Newsletter May 2020

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### Update from the EFSPI President



We are now more than two months down the road of the pandemic in Europe. Many, if not most of you, have been working from home for more than two months which will likely be a record time for many people. It is for me at least! A new normal is emerging; days are filled with even more and more teleconferences, webex meetings, virtual “live” meetings and webinars. Lots of sitting during the day, more than usual, and it is necessary to plan for breaks and exercises during the workday. Otherwise how else to achieve the daily 10,000 steps!! Although governments in many countries are beginning to lift some of the lockdown measures, returning to work in the office will likely not happen for the foreseeable future.

“*The only constant in life is change*” comes from Heraclitus (circa 535-475 BC). Benjamin Franklin (1706-1790) added “*Ones ability to adapt to those changes will determine your success in life*”. I hope you are able to cope well with all of the changes and stay successful in what you do. EFSPI is also busy trying to cope with the changes. We just had an extra Council meeting this week, which is less than a month after previous one, rather than meeting quarterly. There is lots to discuss and

agree upon jointly and so we do. You will read much about it in the various section in the newsletter below. We have decided to cancel all live events and meeting, including the Regulatory Workshop, and plans are in place or being prepared to replace these with webinars. There is a great desire by the EFSPi Council to enable continued scientific discussion and debate. The Statistics Leaders have recently started to meet virtually on a more regular cadence, including actively seeking opportunities to exchange learnings both on key statistics topics as well as on leadership themes experienced during a crisis.

Financially EFSPi will generate less revenues than anticipated for 2020 due to the cancellation of the meetings and workshops. But EFSPi has ensured a solid and secure financial position over the last few years that is helping EFSPi to withstand the loss of revenue caused by the pandemic.

Please let us know where we can help you with during these times. Contact and work with your national EFSPi Council members, they are eager to hear from you as well.

Stay safe!

Stefan

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## **Regulatory**

The final points to consider on COVID-19 and methodological issues for clinical trials from EMA's Biostatistics Working Party is due to be published on the EMA website around the end of May. EFSPi provided comments on the draft version jointly together with EFPIA and other organizations. Click [here](#) to see the key items in the consolidated comments.

EMA has published a discussion paper on The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes. We plan to collect comments jointly with the ESIG on data transparency until end of June. Please send your views to Roland Marion-Gallois ([rmariongallois@celgene.com](mailto:rmariongallois@celgene.com)) or to Christoph Gerlinger ([Christoph.gerlinger@bayer.com](mailto:Christoph.gerlinger@bayer.com)).

The EFSPi Regulatory Statistics Workshop scheduled for the 12-13<sup>th</sup> October 2020 in The Netherlands will not proceed as a face to face meeting. Options to hold virtual sessions are being explored. Further details will follow in subsequent newsletters.

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## Scientific

The Scientific Committee has revised its plans for meetings given the impact by COVID-19. The dates of these meetings will be confirmed in subsequent newsletters and on the EFSPi website. However, these are the meetings planned for 2020:

- A free webinar on **Leadership skills of a statistician**. 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 free joint BBS/EFSPi/PSI webinar organized together with the European SIG “**Estimands in Oncology**” on this topic in Basel, scheduled 29<sup>th</sup> June 2020 9-11.45am CET.
- A free joint EFSPi/BBS webinar on **Health Technology Assessment**, looking back at ‘10 years of HTA’ and looking forward, scheduled 30<sup>th</sup> June 2020 3-5pm CET.
- A free webinar on **Vaccines**, jointly organized with the Belgian Association (SBS/BVS) and the ESIG on Vaccines, to take place in Q4 2020.
- A meeting, likely a webinar, together with the ESIG on **Small Populations** may be held in Q4 2020.

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## ESIG News

### New COVID-19 ESIG

There are numerous statistical challenges to consider for clinical trials impacted by the COVID-19 pandemic and in designing and analysing clinical trials for new medicines to treat the COVID-19 infection. A new COVID-19 ESIG will be having their first meeting in early June. Anyone interested to join please email Chrissie Fletcher ([chrissie.a.fletcher@gsk.com](mailto:chrissie.a.fletcher@gsk.com)).

The Industry Biostatistics Consortium of Statistics Leaders (Pharmaceutical Industry COVID-19 Biostatistics Working Group) is pleased to announce its manuscript on ‘***Statistical Issues and Recommendations for Clinical Trials Conducted During the COVID-19 Pandemic***’ is available as a preprint, click [here](#).

### Vaccines ESIG

The Vaccines ESIG has published their first newsletter for 2020 covering the following topics:

- COVID-19 and the Conferences, Meetings, and Workshops
- Vaccine Workshop in 2020 ASA
- Upcoming vaccines sessions at statistical and other conferences
- Recent publications in the field of statistics of vaccines research
- Website, subscribe etc., Contact us

Click [here](#) to access the newsletter and for more information about the ESIG click [here](#).

### AIMS ESIG

The AIMS ESIG's work with the R Validation Hub has recently yielded a white paper on [R Validation](#). The focus is now on extending the [riskmetric](#) R package and the development of an app in conjunctions with Fission Labs and the R Consortium. Click [here](#) for more information.

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## **Country News**

### **AFP (Germany)**

The APF meeting on November 27<sup>th</sup> and the German Statistics Leaders meeting on November 26<sup>th</sup> are still scheduled as face to face meetings. If needed, a change to a virtual format will be made as late as possible without incurring cancellation fees.

### **BBS (Switzerland)**

#### **Aspects of COVID-19 Pandemic, 3<sup>rd</sup> June 10am-12noon CET.**

The COVID-19 pandemic generates many biometrical problems. This seminar will explore different aspects of the Covid-19 pandemic and implications. The first talk will deal with vaccine development, important for estimating when we finally might get out of lockdown. The second talk then provide insights in pandemic modeling, a major contribution of us in these days. The final two talks will deal with clinical trials specifically targeting Covid-19 disease.

Click [here](#) to register for this webinar. To send questions email Hans Ulrich Burger [hans\\_ulrich.burger@roche.com](mailto:hans_ulrich.burger@roche.com) or use [the chat room during the meeting](#).

### **PSI (UK)**

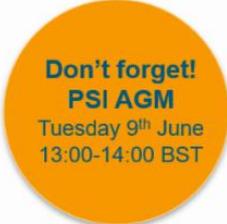
#### **PSI 2020 Conference - Webinar Series - REGISTRATION OPEN**

As announced recently, the PSI Scientific Committee are hosting a series of online webinars which will feature some of the content that was due to be presented at this year's conference. The webinars will run over a four-day period, week commencing 8th June, the same week in which the conference was due to take place.

Registration for these webinars is now OPEN, so please [head to the website to register](#).

The webinars will be free for PSI Members and £100 for non-members (including PSI membership until then end of 2020). Please note that the registration and cost is for the series as a whole, so all 7 webinars.

Further information for each of the speakers can be found on the PSI website under the event page for each webinar. There is also an opportunity for companies to sponsor individual webinars in the series. If your company is interested then please contact [Alex Currie](#) or [Chris Watton](#).

 <b>Monday 8<sup>th</sup> June</b> 14:30-15:30 (BST) <b>Florence Nightingale, pigeon holes and mustard seeds: using data to improve health</b> Deborah Ashby	<b>Tuesday 9<sup>th</sup> June</b> 10:00-11:30 (BST) <b>Career Young Statistician Session</b> Jack Keeler, Ruth Owen, & Georgios Nikoladis	<b>Wednesday 10<sup>th</sup> June</b> 10:00-11:30 (BST) <b>Intersection of Clinical Trials and Real World Data</b> Elizabeth Williamson, Christen Grey & Kirsty Hicks	<b>Thursday 11<sup>th</sup> June</b> 10:00-11:00 (BST) <b>PSI/RSS Prize Winners Session</b> Mike Smith and Jacquie Christie
 <b>Don't forget! PSI AGM</b> Tuesday 9 <sup>th</sup> June 13:00-14:00 BST	<b>Tuesday 9<sup>th</sup> June</b> 14:30-16:00 (BST) <b>In memory of Sally Hollis (former SIG Chair) - Data as an Asset, the re-use of data</b> Data Transparency SIG	 <b>Wednesday 10<sup>th</sup> June</b> 14:30-16:00 (BST) <b>Retire Statistical Significance (!) (?) – How Do We Know What We Know?</b> Stephen Ruberg, Ron Wasserstein & Deborah Ashby	<b>Thursday 11<sup>th</sup> June</b> 14:30-16:00 (BST) <b>Impact of COVID-19 to estimands</b> EFPIA/EFSPI Estimands Implementation Working Group

[Register here](#)

## MEETINGS, WEBINARS AND COURSES

### Introduction to Industry Training (ITIT) Course

Next course starts October 2020. Application deadline 26<sup>th</sup> June 2020.

The 2020/21 course will include 3 sessions in continental Europe and 3 sessions in the UK. The course will aim to describe the drug development process, including sessions on drug discovery, toxicology, data management & role of the CRO, clinical trials, health technology assessment and marketing.

**PSI Member:** £1050 + VAT

**Non-Member:** £1145 + VAT

(Non-Member rate includes PSI membership from September 2020 – December 2021)

[Click here to register](#)



Visit the Video-on-Demand Platform here!



### [PSI Webinar: Chosen or Forced - How to Manage Working From Home](#)

This webinar is aimed both at people who are used to working from home as well as at those who are being asked to work from home for the first time. Not everyone will have an ideal home-working scenario and may also be juggling family needs at the same time. Areas where we need to adapt from the ideal will be discussed.

[Click here to watch](#)

## Podcasts



### [ITIT – an acronym helping you get started in the pharma industry](#)

The Introduction to Industry Training (ITIT) gives the delegates a taste of life across the pharmaceutical industry from early drug discovery to marketing, from CRO to Big Pharma and across the UK and continental Europe. The host company gives his unique perspective from experts in the field.

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### [Core Outcome Measures in Effectiveness Trials - COMET](#)

“A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care.” This clarifies directly what the COMET initiative is about. Listen to this episode while we interview Paula Williamson and Liz Gargon to learn more.

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### [MakeoverMonday - Improving How We Visualise and Analyse Data](#)

This episode helps you to explore different perspectives and approaches to create more effective visualizations. Andy and Eva from MakeoverMonday offer inspiration and a dose of perspective for those who communicate data. Listen to know more about data analysis and visualization of Eva Murray and Andy Kribel of their blog and of course in their book.

*Listen to these podcast episodes now and share it with others who might learn from it.*

*Ciao and be an effective statistician!*

*Alexander Schacht*

[Listen here](#)

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### **Job Opportunities**

Job opportunities exist for [Manager Biostatistics](#), [Senior Manager Biostatistics](#), and [Statisticians in different levels of seniority in clinical development](#).

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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To view previous newsletters please see the EFSPI website in the "[News](#)" area.

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Chrissie Fletcher  
EFSPI Communications Officer

