



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

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## EFSPI Newsletter February 2021

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### **Scientific**

Upcoming webinar on **Wednesday March 3** on *Statistical Leadership*

Everybody seems to talk about leadership these days. Apparently, it is no longer enough to be good at your job as a statistician – you have to be a statistical leader to get on!

We have organised a conservation with Chrissie Fletcher and Andy Grieve. More information can be found on the flyer below and registration is open on the PSI website ([www.psiweb.org](http://www.psiweb.org)).

If you are thinking about your personal development and want to go into 2021 with a bit of a boost, then please attend this webinar.

Register: [www.psiweb.org/events/psi-events](http://www.psiweb.org/events/psi-events)



## Let's talk about statistical leadership

Wednesday 3rd March - 12:00 GMT

- What makes a statistical leader?
- Strategic and visionary thinking for statisticians
- Influencing without authority
- The importance of good communication
- The value of networking

*"We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients"*



Chrissie Fletcher



Andy Grieve

In addition, the Scientific Committee is planning for a number of events in 2021. Although none of them have a confirmed date, these are our intended meeting in preparation for 2020:

- A joint EFSPi/BBS virtual event on **Health technology Assessment**, in June.
- An event on **COVID**, together with the SIG on Vaccines, planned in second half of 2021.
- A meeting together with the SIG on **Small Populations** also in the second half of 2021
- An event on **Decentralised trials** in the last quarter of the year.

At this moment all these events are planned to be online, but as soon as we have more concrete information, we will share with you via the Newsletter and our website.

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## ESIG News

A SIG leaders meeting took place on February 10th 2021. It was an opportunity for SIG leaders to know each other, and to share ways of working and best practice. The meeting was well attended and there was a high level of engagement across a range of topics. In particular, some actions will be taken to establish more visibility, to improve the coordination and the promotion of SIG activities and to develop connections between SIGs.

We now have almost 20 active SIGs, with two new groups getting started: Central Statistical Monitoring/Quality Tolerance Limits (co-chairs [timothy.e.rolfe@gsk.com](mailto:timothy.e.rolfe@gsk.com) and [ssheper@amgen.com](mailto:ssheper@amgen.com)), and Real-World Data (chair: [anny.x.stari@gsk.com](mailto:anny.x.stari@gsk.com)).

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

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



## **Regulatory ESIG**

### **Meeting with MHRA Statisticians (November 19<sup>th</sup>, 2020)**

The Regulatory European SIG (ESIG) has met with the MHRA statisticians face to face for an informal exchange for many years, but unfortunately that (as many other personal meetings) was not possible in 2020. Instead the ESIG met virtually with MHRA statisticians on November 19<sup>th</sup>, 2020. Five statisticians from MHRA and 19 members of the ESIG were present. A wide range of topics were covered during the two hours as follows:

- **Follow-up of topics from the meeting in 2019**
  - Estimands
  - Real World Evidence (RWE)
- **Current statistical issues and potential regulatory statistical concerns of the future**
  - Biosimilars
  - MHRA Regulatory Guidance
  - Patient Focus
- **Areas the ESIG could be leading to improve quality and standards across the industry?**
  - Managing trials during COVID-19
  - Bioequivalence
  - Guideline on Statistical Analysis Plans
- **MHRA's Future Drug Regulation Strategy & international collaborations**
- **MHRA's experience with COVID-19**
- **Complex Innovative Designs (CIDs)**

To full meeting report is available on the [Regulatory ESIG website](#).

*Christoph Gerlinger (EFSPi Regulatory Chair), Jurgen Hummel (PSI Regulatory Chair)*

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## **Country News**

### **BBS (Switzerland)**

**“Statistical Challenges in the Clinical Development of CAR-T Cell Therapies”**

Monday, March 22, 2021 15:00 to 18:00 (CET)

## Free BBS Webinar

Developing CAR-T Cell therapies has unique challenges not observed with traditional drugs. On top of the manufactory and logistical challenges, clinical development is facing unique statistical questions which need to be resolved for delivering view of the treatment effect. The Basel Biometric Section (BBS) is pleased to host a scientific meeting on this relevant and far-reaching topic. The purpose is to bring together experts from the pharmaceutical industry, academia and the European and US regulatory bodies to present the current state of the art and discuss the statistical and other challenges and opportunities of CAR-T cell therapies.

[Click here to view the flyer](#)

[Click here to Register](#)

### **PSI (UK)**

**Registration OPEN for the PSI Conference 2021.**

The PSI Conference will be held online from 21 to 23 June 2021 and registration is now open. Registration for the Online Conference includes:

- Access to:
  - exciting, relevant and up to date presentations and sessions over the three live days
  - additional on demand content
  - the latest research in the e-poster portal
- Continued access to all of the Online Conference content for at least 6 months after the conference, allowing you to view content at your leisure
- Opportunity to attend live networking sessions
- Ability to meet and engage with sponsors and exhibitors
- Ability to catch up and connect with colleagues

**Companies that sponsor the 2021 PSI Online Conference will receive a large number of complimentary delegate passes that will be issued separately.**

**Abstract submissions** are also open with the deadlines of:

- Oral: **Friday 12 March 2021**
- Poster: **Friday 26 March 2021**

Find out more [with link to <https://www.psiweb.org/conferences/about-the-conference>]

**MEETINGS, WEBINARS AND COURSES**



### PSI Webinar: Wearable Technologies

14:00-16:00

#### Who is this event intended for?

Anyone working with digital health data; Clinician, Regulator, Investigator, Academic, Ethics Committee, Statistician, Data Scientist.

#### What is the benefit of attending?

Understand the benefits of continuous digital health data but also its challenges in terms of processing and analysis.

[Register now...](#)



### PSI Leadership Event: Lunchtime conversation with C. Fletcher & A. Grieve

12:00-13:00

**Who is this event intended for?** Any statistician thinking about their personal development.

**What is the benefit of attending?** Hear Chrissie and Andy's thoughts on what makes a statistical leader, strategic and visionary thinking for statisticians, influencing without authority, the importance of good communication, and the value of networking.

[Register now...](#)



### PSI Medical Statistics Careers Event 2021

All day

**Who is this event intended for?** This event is aimed at students with an interest in the field of Medical Statistics, for example within pharmaceuticals, healthcare and/or medical research.

**What is the benefit of attending?** Learn more about the types of opportunities available within medical statistics and have the chance to network with potential employers.

[Register now...](#)

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## **Job Opportunities**

Opportunity for a [Director and Team Leader, 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.....**

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*

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