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

EFSPI Newsletter April 2021

In this newsletter:

EFSPI President

Dear colleagues,

Already a quarter into 2021 and while vaccination programs are running full steam now in Europe, working from home is still the norm; many of you might have "celebrated" a first full year in the home office.

In EFSPI we just had our second virtual Council meeting this year with attendance of all 10 National Associations. We decided that all major events, the Statistics Leaders meeting in June/July, the Regulatory Statistics workshop in September, and the four Scientific Events planned for 2021 will be again virtual, like last year. Having said that, content wise there is no difference with previous years; the organizing committees have developed excellent and very timely proposals, you can read about it in this newsletter.

EFSPI is also pleased to see the uptake of the European Special Interest Groups (ESIGs) (and Working Groups) and the increase in communications sharing the great work they each are doing. These groups spearhead cross-company collaboration on important topics for developing best practices and for establishing guidance to the whole community of statisticians in pharma. EFSPI is supporting these groups by covering a share of the costs of their webinars (for 2021 more than 20 are planned) and through them can serve you all. This is one of the main purposes of our Federation; to promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry.

Stay safe!
Stefan Driessen
EFSPI President

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Scientific

The Scientific Committee is planning for a number of events in 2021:

- A joint EFSPI/BBS virtual event on **Precision Medicine and Health technology Assessment**, **28th June 3-5pm CET**. Click here to get more information and to register.
- An event on **COVID**, together with the ESIG on Vaccines, planned in second half of 2021.
- A meeting together with the ESIG 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

ESIG of the Month – COVID-19

The COVID-19 ESIG have been reflecting on the key learnings in designing, conducting and analysing clinical trials during a pandemic. We are keen to hear from colleagues if the Industry recommendations and regulatory guidelines issued in 2020 to mitigate the impact of the pandemic to clinical trial design and analysis were helpful. Please share any feedback to Chrissie Fletcher (chrissie.a.fletcher@gsk.com) and David Wright (david.wright1@astrazeneca.com). A key focus this year spurred by the pandemic is the acceleration of decentralised clinical trials. A variety of initiatives involving Industry and regulatory agencies are ongoing to assess the implications of clinical trials conducted virtually, including statistical considerations. Further guidance is expected later in 2021.

In collaboration with the Vaccines ESIG and through the numerous webinars held in 2020, much has been learned about the design and analysis of COVID-19 vaccine clinical trials. In Q1 2021 there has been a focus in the ESIG on the different vaccines approved with respect to their efficacy and safety profiles, and how the emerging potential risks are being presented and communicated. Many

professional societies have set up COVID-19 taskforces, for example, the Royal Statistical Society in the UK, to provide best statistical practice in areas such as data collection, diagnostic or treatment studies, modelling and forecasting. Many leading academic statisticians are contributing to efforts to effectively communicate COVID-19 related summary data to the public to help them understand risks of COVID-19 infection versus vaccine side effects.

The long-term consequences of COVID-19 infection is currently not well understood with an increasing focus on assessing the burden to patients of long-term health issues (Long COVID). The impact of existing and new variants is also unclear and will continue to disrupt societies and impact clinical research. A number of treatments for COVID-19 infection are emerging and a variety of platform trials are underway to help accelerate testing existing or new medicines as potential COVID-19 treatments.

The COVID and Vaccines ESIGs are looking forward to celebrating the positive impact statisticians have had on the fight against COVID-19 at the PSI Conference (Monday 21st June 2-3.30pm BST) with the following presenters: Geert Molenberghs (Universiteit Hasselt and KU Leuven), Kenneth Koury (Pfizer), Ian Hirsch (AstraZeneca), Andrew Thomson (EMA). Also, don't miss the opening Plenary session of the PSI Conference "Covid-19: Visualising the Pandemic" with *Alan Smith and Ian Bott (Monday 21st June 9.15-10.15am BST).*

Chrissie Fletcher (GSK) and David Wright (AZ)


Regulatory ESIG

6th EFSPI regulatory statistics workshop

We are happy to announce the 6th EFSPI regulatory statistics workshop. We plan webinar sessions on three days:

Monday, 13rd September 2021, 14.00-17.00 CET
Tuesday, 14th September 2021, 11.00-14.00 CET
Wednesday, 15th September 2021, 9.00-12.00 CET

The topics that we will discuss include:

1. Complex innovative designs: Where is their place in drug development?
2. Real-world data - using their potential.
3. Decentralized trials: What is the impact on evidence generation?

More details are available here: https://www.efspi.org/EFSPI/Events/Regulatory_Meetings/6th_efspi_workshop_on_regulatory_statistics.aspx

We invite everyone to block their calendars!

Kaspar Rufibach, on behalf of the local organizing and scientific committee.

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. Attendees for the break-out sessions are requested to have expertise or experience of CCTs. Two of the break-out sessions will discuss statistical considerations relating to CCTs. Click here to see more details.

Chrissie Fletcher on behalf of the EFPIA Complex Clinical Trials Team

Meeting with Biostatistics Working Party

The Regulatory ESIG is planning to meet with the Biostatistics Working Party in October 2021. This annual meeting will be similar to the one held in 2020 with multiple associations and professional groups coming together to discuss statistical topics. Further details will follow.

Other Regulatory News

Christoph Gerlinger was appointed by the EU's statistical agency Eurostat as member of the Expert Group "Facilitating the use of new data sources for official statistics". https://ec.europa.eu/eurostat/cros/content/expert-group-facilitating-use-new-data-sources-official-statistics_en

Christoph will bring his expertise in sharing clinical data and in the statistical aspects of data protection to the table.

Christoph Gerlinger (EFSPI Regulatory Chair), Jurgen Hummel (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)

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Country News

PSI (UK)

PSI Online Conference 2021 update

The PSI Conference programme is now available on the website. We have 3 plenary sessions and 27 parallel sessions spread out over the three days, along with on demand content and posters.

With less than 10 weeks to go – don't forget to register!

Paul Terrill PhD, PSI Conference Chair

Find out more

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.

Statistical Excellence in the Pharmaceutical Industry Award

The deadline for nominations for the 2021 Award for Statistical Excellence in the Pharmaceutical Industry, jointly run by PSI and the Royal Statistical Society (RSS) has been extended to the 11th May 2021. Nominees can be based anywhere in the world and do not need to be a member of PSI or the RSS. The award will be presented at the annual PSI AGM in July. Click here to find out more.

MEETINGS, WEBINARS AND COURSES

PSI Missing Data in Clinical Trials - Past, Present and Future

4 May: 10:30-13:30, 5 May: 9:00-12:00

Who is this event intended for? Statisticians involved in designing and analysing clinical trials.

What is the benefit of attending? Gain awareness of the increasing importance of appropriate missing data handling in clinical trials by learning about state of the art methodology and recent case studies.

Register now...

PSI Webinar: Oncology TED Talks (with interaction)

25 May: 14:00-17:00

Who is this event intended for? All statisticians from research/academia /Pharma industries, especially those working in Oncology.

What is the benefit of attending? To hear more about the uses for ctDNA in Clinical Trial Design, integration of real world data in early development studies, multiplicity in confirmatory clinical trials with master protocol designs and thoughts on late-onset toxicities in dose-finding studies.

Register now...

PSI EIWG Webinar: Estimands in Oncology - How and Why

1 June: 15:00-16:30, 2 June: 9:00-10:30

Who is this event intended for? Anyone working in clinical trials: Clinician, Regulator, Investigator, Academic, Ethics Committee, Statistician.

What is the benefit of attending?
Through a case study you will understand the benefits of using the estimand framework to describe the diversity of patient journeys addressing the right questions in clinical trials.

Please note: this event takes place on both the 1st and 2nd June, but will entail exactly the same content.

Register now...

PSI Training Course: Data Monitoring Committees (DMCs)

8 June: 9:00-13:00, 9 June: 14:30-16:30, 10 June: 9:00-13:00

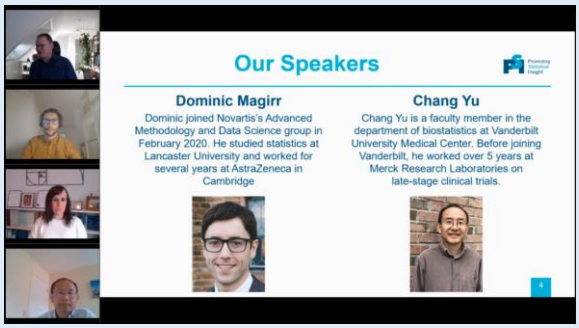
Who is this event intended for? Statisticians working on clinical trials which require a DMC.

What is the benefit of attending? Understand the different roles and responsibilities within a DMC, and have the chance to participate in a DMC within an interactive workshop.

Please note: Places for this course are limited and in high-demand, so please ensure you are able to attend all sessions before booking.

Register now...

Podcasts & Webinars



PSI Journal Club Webinar: Survival Analysis
Watch this Journal Club webinar to hear Dominic Magirr (Novartis) and Chang Yu (Vanderbilt University) present their recent work. With the webinar chaired by Jennifer Rogers (PHASTAR).

PSI VisSIG Wonderful Wednesday 14: Mobile App Usage
Irene de la Torre Arenas presents the results of last month mobile app data challenge. The change of individual app usage over time has been visualised in very different ways as well as its impact on individual symptoms of COPD. The discussion centre around the usability of the respective display type for the given purpose. All visualisations are available on the Wonderful Wednesday blog.

Welcome to Sam Gardner and insights into non-clinical statistics
Let's welcome Sam Gardner as our new co-host for our podcast show! In his first episode as a co-host, we spent some time getting to know more about him.

How AI helps us with patient insights
Everybody talks about AI, but where are the actual use cases? In the episode today, I'm talking with Dooti Roy about AiCure and how will this change the way we analyse studies.

How to get the most out of a virtual conference
As the pandemic continues to affect the community's ability to meet in-person, virtual conferences adapt

and develop to create space for companies. Now, there is much more emphasis on virtual settings, and there are many new tools available to improve the virtual conference experience.

Listen to these episodes and share them with your friends and colleagues!
Ciao and be an effective statistician!
Alexander Schacht

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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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