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

EFSPI Newsletter September 2020

In this newsletter:


Regulatory

EFSPI Regulatory Statistics Workshop

The EFSPI Regulatory Statistics Workshop is taking place as virtual sessions on the 12-13th October 2020 14:00-16:35 (CEST). The topics for each webinar are as follows:

Webinar 1: Data monitoring committees – evolving their role in a changing drug development landscape
Webinar 2: Estimands – emerging questions now that we are using the framework

Already 300+ participants are registered. Click here to view the program and to register.

Meetings with Regulatory Statisticians

Members of the regulatory ESIG will participate in a virtual meeting of EMA's Biostatistics Working Party (BSWP) with several industry groups on October 2nd. Topics on the agenda include:

1) Impact of COVID-19 on methodological aspects of on-going clinical trials
2) Statistical methods applied to the quality of medicines

3) Complex Innovative Clinical Study Design (CID): challenges and possible pilot programme in the context of EMA Regulatory Science Strategy 2025 objectives (see below)

A summary of this meeting will be provided in the October's EFSPI newsletter.

The regulatory ESIG plans to hold a virtual meeting with the MHRA statisticians as well this fall, but no date has been fixed yet. If you have topics you would like us to address please contact Jürgen Hummel Jurgen.Hummel@ppdi.com or Christoph Gerlinger christoph.gerlinger@bayer.com .

New guidelines

EMA has published a draft Guideline on registry-based studies for a three-month public consultation. Please send your comments to Roland Marion-Gallois Roland.Marion-Gallois@bms.com and Florian Voß florian.voss@boehringer-ingelheim.com by the end of November 2020.

FDA has published a final guidance on Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment Covid https://www.fda.gov/media/142143/download . There is no formal comment process for FDA's COVID-19 related guidances.

FDA has also published a draft guidance on Pharmacokinetics in Patients with Impaired Renal Function. https://www.fda.gov/media/78573/download. The ESIG does not intend to comment but please contact Jürgen Hummel Jurgen.Hummel@ppdi.com or Christoph Gerlinger christoph.gerlinger@bayer.com if you feel we should.

EMA Regulatory Science Strategy to 2025

In the EMA regulatory science strategy to 2025 released in July 2020 six key areas of focus were highlighted:

- Availability and accessibility of medicines
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- Supply chain challenges
- Sustainability of the Network and operational excellence

Two of these areas, data analytics, digital tools and digital transformation, and innovation, are highly relevant to Biostatistics. The first area will involve standardizing data collected in routine healthcare systems, and building sustainable capabilities including statistics, epidemiology, real world data and advanced analytics. The second area will involve developing competencies to support innovation across medicines development, fostering collaborative evidence generation, leveraging innovation in regulatory science and enhancing collaboration with experts and academic groups. Important for clinical trials is supporting innovation and digitalization including strengthening expertise in the regulatory systems for complex designs, use of data analytics and real-world data. Click here to read the EMA regulatory science strategy to 2025.

EFPSI is partnering with EFPIA on advancing innovation in clinical trials through the Clinical Research Expert Group and the Complex Clinical Trials (CCTs) sub-team chaired by Chrissie Fletcher (GSK). In September, representatives of the CCT met with representatives from EMA, Heads of Agencies Clinical Trials Facilitation Group (CTFG) and the EU Commission to discuss current challenges with

CCTs in Europe, share recent case studies, and discuss possible solutions. Next steps and subsequent follow-up activities are being agreed and will be shared in due course.

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

back to top

ESIG News

Data Transparency

The RSS Medical Section is holding a webinar on "Protecting *confidentiality and privacy in clinical trial and medical data sets"* on Wednesday 07 October 2020, 3.00PM - 6.00PM with Katherine Tucker from the ESIG presenting. Use this link to register.

Vaccines

The Vaccine SIG is hosting a webinar on Thursday 15th October 15:00 - 17:00 BST (16:00 - 18:00 CET), which will feature two presentations on topics relating to methodological developments in vaccines research. Frank Harrell, Vanderbilt University, will present 'Sequential Bayesian Designs for Rapid Learning in COVID-19 Therapeutic Trials'; and Dean Follmann, NIH, will present on 'Statistical Aspects of COVID-19 Vaccine Trials'. Join us for this insightful and highly topical webinar, click here to register.

Estimands in Neuroscience

A joint ESIG/BBS seminar on the use of estimands in Neuroscience will be held on Tuesday, 3rd November 2020, 13:00-16:00 CET. Neuroscience is a heterogeneous therapeutic area in which development pathways and study analyses can substantially differ between different indications. Efficacy is usually based on longitudinal assessments which makes the application of the estimand framework specifically interesting and rich with many specific aspects from which we all can learn a lot. To register click here.

back to top

Country News

FMS Sweden

FMS will be holding an online AUTUMN MEETING Nov 13, 2020 on the topic "Current statistical topics concerning Covid-19". Presentations will include academia (Department of Mathematics, Stockholm University), industry (AstraZeneca) and governmental authorities (Statistics Sweden, National Board of Health and Welfare, and Public Health Agency of Sweden).

IBIG (Italy)

IBIG are hosting the following webinars: Every Friday h. 10,00 – 12,30 (CET)

Date	Topic
2 October	Quantitative Decision Making (QDM) in the Clinical Drug Development
9 October	SAS, R, Python – Differences, Similarities and Potentialities of Widely Used Stats Software
16 October	Clinical Trial Management during the COVID-19 Pandemic – Guidelines and Practical Impacts
23 October	Taxonomy of Subgroup-related Analyses and Issues in Clinical Trials
30 October	Data Visualization for a Better Communication with Non-Stats People

On the 7th October 2020, h. 10.00 – 17.30 CET: 7th Italian CDISC User Group Network have their Annual Meeting. See here for more details.

PSI (UK)

Winner of 2020 pharmaceutical award announced

We are delighted to announce the winner of the 2020 Statistical excellence in the pharmaceutical industry award, presented jointly by the RSS and Statisticians in the Pharmaceutical Industry (PSI). ***Find out about our winner...***

Virtual issue to aid statisticians in promoting the benefits of estimands

Pharmaceutical Statistics has just published a virtual issue on estimands. These articles should help statisticians promote best practices when discussing the treatment effect to be estimated and discuss how post-randomization events can impact the goal of a study.

There is still a long way to go before the full potential of the estimand framework is fully realized and embraced by the wider community, and statisticians have an opportunity to lead, inspire and make a difference.

Read it here

MEETINGS, WEBINARS AND COURSES

PSI Webinar: Patient preference studies

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14:00 - 15:30

Who is this event intended for? Anyone keen to learn about patient preference studies and their application.

What is the benefit of attending? Learn what a patient preference study is & how it can inform regulatory decision-making.

Register now...

PSI Vaccine SIG Webinar: Statistical Topics on COVID-19 Therapeutic and Vaccine Clinical Trials

15:00 - 17:00

Who is this event intended for? This webinar is intended for statisticians and data scientists involved in the design and analysis of clinical trials for coronavirus disease treatment or prophylactics.

What is the benefit of attending? Attendees will have the opportunity to hear from two key experts in the field about novel Bayesian techniques, as well as selected topics on vaccine induced correlation with immune response consequences of a successful vaccine, on the conduct of ongoing placebo-controlled trials.
Register now...

Joint PSI, EFSPI & ASA BIOP Webinar: Estimands

14:00 - 16:00

Who is this event intended for? The event is intended for statisticians involved in the design of clinical trials (particularly Phase II and III) in all therapeutic areas, from industry, CROs and academia.

What is the benefit of attending? The audience will gain insight into the use of estimands in practice and regulatory considerations.

Register now...

Podcasts & Webinars

PSI Webinar: Using Visualisation to help make decisions

This webinar features presentations from 3 speakers on the topic of Using Visualisations to Help Make Decisions.

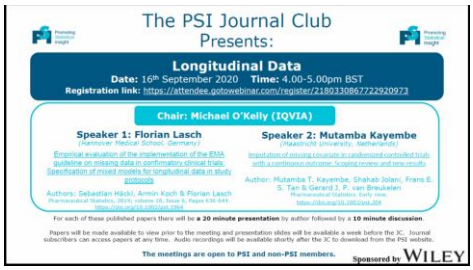
- Caroline Caudan presents 'Interactive statistical monitoring to optimize review of potential study issue with R-Shiny'
- Paolo Eusebi presents 'Effective visualization of uncertainty – Where we are and where to go'
- Michael O'Kelly presents 'Subgroup analysis: a look at the SEAMOS approach (Standardised Effects Adjusted for Multiple Overlapping Subgroups)'.

Watch here

PSI VisSIG Webinar: Wonderful Wednesdays Ep.7

How to display safety data? This month's challenge has shown there are very different ways to visualize adverse event data. Although the example data set was from a two-arm study and relatively simple, the display of type of AE, frequency, timing, severity and seriousness is not easily combined in one plot.

Watch here



PSI Journal Club Webinar: Longitudinal Data

Watch this Journal Club webinar on "Longitudinal Data". Florian Lasch (Hannover Medical School, Germany) and Mutamba Kayembe (Maastricht University, Netherlands) presented their recent work. The webinar was chaired by Michael O'Kelly (IQVIA).

Watch here

My personal leadership principles

Why do you need personal leadership principles? How can you refine and reflect them? What kind of leader do you want to be? Is it possible to be a leader even without a title? In this episode, I talk about personal

leadership and this is not being a leader by position, but by principle.

4 steps to engage successfully with senior stakeholders and committees

Do you currently run an initiative?
Do you want to get support or budget for an initiative? In this episode, I talk about these 4 important pieces of advice if you want to engage with key people in your organization.

10 reasons for career failure and what you can do about it

Napoleon Hill is an interesting author and quite controversial but still good content to reflect upon. In this episode, I want to reflect on: Why do people fail in their careers? What hinders us from getting to the career goal set we have? How can we avoid doing the same thing in our own life?

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

Non-PSI News

ISOQoL (International Society for Quality of Life) forming a new Statistics SIG

ISOQoL Statistics SIG: This SIG connects statisticians working in the field of quality of life and provides a platform for communication, interaction and collaboration. Our aim is to identify and progress key areas for research and provide workshops and training for the wider ISOQOL membership; one of the planned workstreams will be around estimands.

Its inaugural meeting is at the ISOQoL **Virtual annual conference in October 2020** - they are welcome to new members.

Find out more...

We are planning a webinar series that will start on October the 8th and 9th 2020, with two consecutive webinars on the days that would have been COMET VIII, followed by once a fortnight after that. More details about forthcoming webinars will be announced as they become available.

If you have any questions, please email: info@comet-initiative.org

Sessions:
1."Are you still troubled by research waste?"
Thursday 8th October, 12:00 - 13:00
Click **here** to register.

2."What the COMET database tells us about the development and content of core outcomes sets"
Friday 9th October, 13:00 - 14:00
Click **here** to register.

3."Including patients in COS development"
Tuesday 20th October, 14:00 - 14:45
Click **here** to register.

For more information, please visit the website.

back to top

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.

back to top

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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.

back to top

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

back to top