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

EFSPI Newsletter November 2020

In this newsletter:


Regulatory

Meetings with Regulatory Statisticians

The regulatory ESIG held a virtual meeting with MHRA statisticians on the 19th November 2020. Topics for discussion included a follow-up of actions from the previous meeting in late 2019, current statistical issues of focus, MHRA future drug regulation strategy, MHRAs experience in 2020 arising from COVID-19, and complex and innovative trial designs. A summary of the meeting is being drafted and key highlights will be shared in future newsletters.

New guidelines

MHRA has issued new Guidance on minimising disruptions to the conduct and integrity of clinical trials of medicines during COVID-19.

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

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ESIG News

Vaccines ESIG

The Vaccines ESIG is pleased to announce a webinar on ***Developing COVID-19 Vaccines*** taking place on **Thursday 10th December 2020 at 15:00 - 16:00 GMT**, Speaker**: Scott Patterson** *(Sanofi)*

Traditional vaccine clinical development is an undertaking involving meticulous, multiple studies in multiple populations at risk of infection and disease over multiple years. SARS-CoV-2 and COVID-19 vaccine development is following this traditional development pathway, but accelerated Phase I-II-III clinical programs are being applied (c.f., USA FDA guidances 2020). This is not the first-time vaccines have been manufactured and tested quickly to meet a public health crisis (1976, 2009). Selected statistical concepts pertaining to vaccine efficacy and safety, relevant during the design and implementation of such crisis programs, will be discussed. Click here to register.

AIMS SIG update on industry progress towards using R

The pharmaceutical industry has been understandably cautious to accept R software due to concern with how to ensure adequate validation and version control, such that we can obtain reproducible and reliable results. However, there is building momentum. Below is a summary of some of the activities and collaborations which aim to provide all users with clearer guidance and tools to enable the use of R in our industry. If you are working using R in the industry, then please help to shape our future by collaborating with one or more of these projects.

R/Pharma conference The conference team put on a great 2020 conference during October. All online, it allowed people to join all over the world with talks from the US, Europe, and even Australia. If you missed out and want to see most of the talks are now online! [https://www.youtube.com/channel/UCT2TrH2M4zbRJZMH6iusyBQ]. Also, checkout their github page for slides [https://github.com/rinpharma/2020_presentations]. The next big conference is RStudio conference which will be held virtually January 2021, with registration opening soon. [https://rstudio.com/conference/]

R Validation Hub. Produces general guidance on using R and ensures collaboration of various wider teams to ensure no duplication of effort. Created a package risk assessment framework in the form of a white paper https://www.pharmar.org/white-paper/.

Riskmetric package has been created (https://github.com/pharmaR/riskmetric) and associated R Shiny App to interact with the package (https://www.pharmar.org/blog/2020/08/05/2020-08-05-risk-assessment-application/). This allows users to create a report of risk metrics so that a risk assessment of packages can be undertaken and documented. The first CRAN version of riskmetric is expected by end of 2020. See: https://www.pharmar.org/ for the Hub's activities.

Join the mailing list to be invited to attend the hubs meetings where you'll get updates on progress and how you can help collaborate. Use this link to join the mailing list: https://lists.r-consortium.org/g/RConsortium-Validation-Hub

R consortium RTRS. This working group is exploring the production of R Tables for regulatory submissions (RTRS): To join this group you can sign up at: Rconsortium-wg-rtrs@lists.r-

consortium.org.

PHUSE. Led by Mike Stackhouse (Atorus) and Michael Rimler (GSK), this project seeks to develop a framework for assessing differences in statistical modelling implementations across multiple programming languages. The project team will apply this framework for common use cases in clinical trial analyses and their implementations in R and SAS. The team also aims to deliver a repository of sample code which demonstrates each use case. The objective is to provide guidance on how to generate confidence in a particular implementation, independent of programming language and the differences which may naturally occur when comparing results across multiple languages. If you are interested please contact Mike.Stackhouse@atorusresearch.com or michael.s.rimler@gsk.com.

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Country News

PSI (UK)

Medical Statistics Careers Event 2021 is going Virtual!

Due to ongoing COVID-19 restrictions we have made the decision to proceed with a virtual event for 2021. We are still planning to bring you our same schedule of presentations and exhibitor session, with the event hopefully taking place in **February 2021**. Keep an eye on our website and social media channels for further details of the event. If you want to stay up to date with the latest news please sign up to our distribution list via the button below.

Sign up

Volunteer role available - Hackathon Lead

We are currently looking for someone to join the communications committee as the hackathon team lead. This will initially be a 6-month post over which you will work with the other PSI committees to arrange and run the two hackathon events. We are looking for someone who is familiar with the PSI community and who has some knowledge or experience in running a hackathon (or similar) event.

Find out more

MEETINGS, WEBINARS AND COURSES

ToxSIG Webinar: Combining Sexes
14:00 - 15:00

Who is this event intended for?
Anybody keen to learn about the combining of sexes for statistical analysis in Toxicology, & the associated guideline recommendations.

What is the benefit of attending? Gain an overview of regulatory guidelines & the application to both ECG Data/DART Data, whilst looking at the consideration of sex in Toxicology.

Register now...

PSI Webinar: Innovative approaches in the development of paediatric medicines
13:00 - 15:00

Who is this event intended for?
Statisticians involved in the development of paediatric medicines in all therapeutic areas, from industry, CROs and academia.

What is the benefit of attending? The audience will gain insight into the challenges of paediatric drug development and how to address them.

Register now...

PSI Webinar: Risk Based Monitoring & QTL's
14:00 - 16:00

Who is this event intended for?
Anyone who would like to learn more about risk-based monitoring and how QTLs are being defined in practice.

What is the benefit of attending?
Receive an introduction, overview and some examples of how some companies are implementing QTL's and a chance to ask the panel some questions.

Register now...

Vaccine SIG Webinar: Some considerations on developing COVID-19 Vaccines
15:00 - 16:00

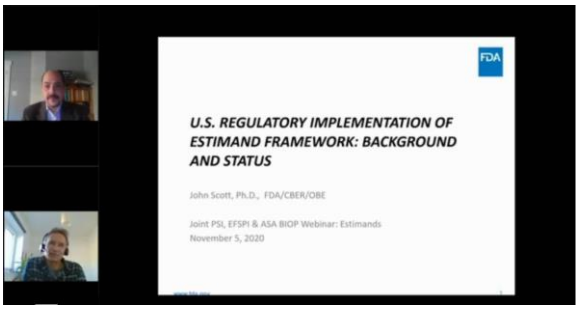
Who is this event intended for?
Statisticians interested in the statistics of crisis vaccine clinical studies, like those being done for COVID-19.

What is the benefit of attending? Learn of statistical observations on crisis vaccine clinical development that are important to understand data generated in COVID-19 vaccine development and other crisis clinical vaccine programs.

Register now...

Stay tuned - more events to be announced soon!

Podcasts & Webinars



Joint PSI, EFSPI & ASA BIOP Webinar: Estimands

PSI, the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) and the Biopharmaceutical Section of the American Statistical Association (ASA) are jointly organising a webinar on Estimands in Practice. Speakers from regulatory authorities (FDA and EMA) and industry will present on their experience on the recent ICH E9 (R1) guidance.

Watch here

Wonderful Wednesday Webinar 9: Mediator Data

Zachary Skrivanek guides through a number of data visualisations explaining a mediated treatment effect on patient reported quality of life. In addition, the problem of missing data should be handled within the graphical representation.

Watch here

What we can learn from Taylor Swift about creating data visualizations

In this episode, we are talking about Taylor Swift and visualizations. Does it seem like a very unreasonable thing? I thought so as well but then I read this interesting LinkedIn post where I laughed hard, but it really made sense!

The benefit-risk tolerability measure – a new way to reach insights into benefit-risk and more
In this episode, you will learn a new concept which also is related to minimal clinical meaningful differences and helps to assess the impact of various adverse events on the patient.

How to improve your work by applying the principles of design thinking
What's in it for statisticians and data scientists? What are the different aspects of design thinking? What are the examples for application of design thinking within data science and statistics?
Design thinking is an interesting topic and is becoming more popular these days. Join Victoria and I while we discuss this.

Alexander Schacht (Effective Statistician)

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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.

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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.....

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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