European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter December 2020

EFSPI wishes everyone a Merry Christmas and to stay safe with good health.

In this newsletter:

End of Year Remarks

This is the last Newsletter from EFSPI in 2020; a year you will most likely never forget. Lockdowns, overloaded hospitals, working from home for months, restricted international traveling, many more video-conferencing, vaccines, clinical trial disruptions, telehealth are just some of the examples of the many issues we've faced. In 2020 in all kind of ways we have all been impacted by the novel coronavirus SARS-CoV-2, better known as COVID-19.

Nevertheless, my first thoughts go out to the relatives of those who have died from this new disease, and especially if this has impacted you. I am sorry for your loss and my sincere condolences. It is unreal to say a final farewell in a very limited group, at a social distance. I wish you great strength.

When looking at our daily work, also there nothing normal. Most of you will by now have spent almost nine months of working from home, maybe more than you ever had before. And the work itself came with changes due to the impact of the virus on clinical trials, an area, I know, a lot of you work on daily. Missed hospital visits, drug delivery issues, recruitment delay or halts, and the impact of this all on the statistical analysis and drawing of conclusions.

Yet it was good to see how the statistical community reacted on this. Many of the EFSPI national organisations held virtual meetings to discuss the impact of COVID-19 on clinical trials and ways how to mitigate the risks to the value of the study, also spurred by the release of regulatory guidance on this area. EFSPI contributed to this in the annual regulatory statistics meeting and in by supporting meetings led by the national organisations. The Statistics Leaders Forum convened several times to discuss the impact and how to best address it within our community. All these meetings had to be virtual, which was also a big change from how we normally operate, meet, and co-operate. It led, I think, back to something fundamental about our work: given the impact to data, for instance of a clinical study, assess the risk and mitigate as good as possible to still retain the integrity of results realizing that it is data coming from participants, that were possibly in an even more difficult circumstance than ever before.

Further, I would like to thank you all for the extra efforts to address these issues and for the additional work many of you have achieved in supporting the development of medicines, vaccines, and diagnostic tests to help fight the virus. There is emerging hope that we will have a better, safer year in 2021. I hope you have found 2020 more meaningful than usual and that it has been both gratifying and consoling while many statisticians have contributed their knowledge and skills to fight the virus.

Let me end by wishing you all, in very different and difficult circumstances, very good holidays and hope you will be able to be amongst a few of your loved ones.

Stefan Driessen, EFSPI President

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Regulatory

Denmark opened the first national data analytics center for health care data in Europe. The recording of a webinar on how to access the Danish healthcare data is available from https://investindk.com/webinar-ondemand/webinar-series-on-personalized-medicine/unique-possibilities-for-use-of-danish-healthcare-data

The Regulatory ESIG commented on EMA's "Guideline on registry-based studies". The final comments will be put on the EFSPI website.

Thanks to all the support from the regulatory ESIG members in 2020.

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

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ESIG News

The ESIGs have provided end of year summaries of their achievements in 2020. Thanks to all the members of the ESIGS for their contributions and support in 2020. Click here to view information about each ESIG.

Vaccines ESIG

The Vaccines ESIG has been incredibly busy in 2020. The ESIG has kept EFSPI aware every month of the latest news, upcoming COVID-19 Conferences, Meetings, and Workshops. The ESIG has supported and presented at a variety of workshops, highlighted important publications and articles of interest in the field of statistics of vaccines research, and provided links to recordings of key events for reference.

To see the latest methodological developments in vaccines research use this link to view a recent webinar recording: https://www.psiweb.org/vod/item/psi-vaccine-sig-webinar-statistical-topics-on-covid-19-vaccine-and-therapeutic-clinical-trials.

Fabian Tibaldi (GSK)

COVID-19 ESIG

In partnership with the Vaccines ESIG the COVID-19 ESIG has been meeting monthly to discuss latest news and trends relating to clinical research in the era of COVID-19. Since the spring and the start of the pandemic there have been many webinars, meetings and publications held discussing the statistical issues relating to the impact of COVID-19 to clinical trials. Regulatory agencies have released a variety of guidelines in response to the pandemic and these continue to be updated.

The ESIG has been discussed the statistical designs, study endpoints and planned methods of the emerging vaccines and treatments for COVID-19.

In 2021 there will be a focus on what have we learned in designing, conducting and analysing clinical trials during a pandemic and what

Chrissie Fletcher (GSK) and David Wright (AZ)

Toxicology ESIG

During 2020 the Toxicology SIG continued to provide webinars on hot topics. Our 3 planned webinars covered Data Science, Label-free classification of ciliated cells using Deep Learning and Reproducibility from Discovery to Clinical Research. Alongside these, plans were in place for a face to face workshop, initially for March, then delayed and ultimately cancelled. The workshop was replaced by 2 additional webinars, which covered 2 of the topics were we going to discuss face to face. In addition, work towards a joint Toxicology SIG paper progressed and we are very close to having a final document to submit. While we haven't been able to meet, as we normally would, we have continued to have

regular virtual meetings and discussions and are now well in to planning for our 2021 workshop which we hope to hold face to face, coronavirus allowing!

Gareth Thomas (Covance)

Data Transparency ESIG

The Data Transparency ESIG presented a session at the virtual PSI Conference in July. This session was in memory of our founding Chair Sally Hollis. Speakers from a mix of industry and academia shared the privacy issues and challenges of re-using clinical trial data and examples of where this work has resulted in new insights. A recording of the session is available on the PSI website. A short article based on the content is in development for publication in the new year (SPIN).

Members of the ESIG have drafted and submitted a manuscript to Pharmaceutical Statistics titled "Anonymizing Data for Secondary Use" which will serve as an overview and reference on this topic. We hope that this will be published in 2021. The ESIG continues to encourage volunteers to join us.

Hope you have a relaxing Xmas and New Year break,

Rebecca Sudlow (Roche)

New Starters ESIG

On a crisp February morning, meandering through the bustle of central London, I headed to the New Starters' SIG annual face-to-face networking event. 40 statisticians from across biotech and pharma met in King's College London's Waterloo campus for an afternoon of networking activities and ice breaker events. The afternoon began with a keynote talk from Dr Kimberly Goldsmith on her work in Clinical Trials, psychological therapy and communication with the media. Delegates broke out into small teams to tackle a series of data analysis challenges – did Game of Thrones really get worse over time? Do the England football team win more often at home than away? Have UFO sightings got more common over time? Can Punxsutawney Phil – of Groundhog Day fame – really predict the start of spring? The day finished with presentations on each of these questions, with a staggering breadth of innovative data visualisation approaches and effective teamwork clearly on display.

In 2021 we seek to capture the successful elements of the last event – the contacts made, the ice broken, the technical skills exchanged – and we are working with MCI to move this online.

Jack Euesden (GSK)

AIMS ESIG

2020 Key Objectives and Progress Summary.

Key objective 1: Act as an intermediary between groups exploring the use of R in our industry and share this information with the wider PSI community. AIMS during 2020 is excited to support and collaborate with the following projects:

- 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/. Created a riskmetric package (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 any day now! 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. 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: https://lists.r-consortium.org/g/Rconsortium-wg-rtrs

- 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

Key objective 2: Provide a central storage site containing links to documentation and demonstration of R's capabilities and latest regulatory advice/industry key opinion leaders. See: https://psiweb.org/sigs-special-interest-groups/aims for further information on our other objectives, on R training and to download any of our articles that have appeared in PSI SPIN over the last few years. Look out in a future PSI SPIN for our article on R licenses and what you need to know about re-use of code. If you want to join us, get in touch at lyn.taylor@phastar.com

Lyn Taylor (PHASTAR)

Estimands in Oncology ESIG (also an ASA Scientific Working Group)

Despite the many challenges in 2020 the SIG was able to relevantly contribute to the implementation of the estimand addendum in drug development in oncology and beyond. Key achievements are:

- The intercontinental team spirit that allowed to come up with a rapid response to COVID-19 pandemic: a slide deck discussing the impact of the pandemic on a trial's estimand was published on the webpage less than five weeks after WHO declared the pandemic. A paper followed only a few weeks later.

- Several publications of the SIG were published this year, and several more are in their last rounds of revision.

- The SIG organized two webinars that brought together drug developers, academics, and regulators to discuss topics around estimands in oncology and beyond:

    - Estimands addendum is final: Anything new for oncology?: The highlight here was that several clinical colleagues contributed as presenters and panellists.

    - RCTs meeting causal inference: principal stratum strategy and beyond.

- The SIG organized sessions and was invited to speak at virtual US conferences (JSM, ASA-FDA workshop, Deming conference on applied statistics). Further talks were given at several occasions.
- The SIG organized TCs with seven Health Authorities (FDA, HC, Swissmedic, China, Japan, Taiwan, MHRA) to share its work and get input on future directions.
- Set up a webpage (www.oncoestimand.org) to foster sharing of information and generated content such as presentations and publications. As of today, the SIG has 54 members (20 from Europe, 29 from US, and 5 from Asia) representing 28 companies.

Currently the SIG is regrouping in task forces dedicated to eight topics that are considered relevant to develop implementation of the addendum further in oncology clinical trials. So, expect more output in 2021!

Kaspar Rufibach (Roche)

Decision Making ESIG

In 2020, the ESIG Quantitative Decision-Making (QDM) focused on writing two manuscripts on the awareness, the use and practical aspects of QDM methods in pharmaceutical development. These manuscripts extend the content of two webinars the SIG provided end 2019, and they will be submitted soon. We also have just created a new working group on methods for QDM at the portfolio level, which will start its activities in 2021. Few members left the SIG and new members joined, so we remain a motivated group of 18 members from industry and academia. We maintain our awareness on QDM methods by having presentations of internal members or external guests at each of our plenary meetings.

Gaelle Saint-Hilary (Sanofi)

HTA ESIG

The HTA ESIG celebrated its 10-year anniversary in early 2020. 2020 the HTA ESIG met every other month to share latest news and trends in HTA. The ESIG began with 11 members from 9 companies/consultants. In the statistics community few statisticians understood HTA so there was a great opportunity to show how statistics can influence and be involved in HTA strategy and HTA analytics. At the Statistical Leaders 2010 when quizzed about their views about HTA there was a sense of '"…I don't understand what my Health Economics colleagues say, it is like they are speaking a different language…'.

The ESIG has presented at many scientific conferences on hot topics over the years. Each year an annual 1-day HTA meeting has been organised to share case studies. Publications have been written relating to HTA best practices, methods, subgroups, indirect comparisons, PROs, treatment switching. The ESIG has reviewed HTA guidelines from local HTA agencies and pan European HTA agencies. Over the years several round table Q&A sessions have been held with invited guests to maximise the opportunity for statisticians to influence and make a difference in HTA activities. Significant progress has made to increase the awareness and understanding of HTA in the statistics community.

Currently the ESIG has 40+ members from 25 companies/institutions. Thanks to everyone who has supported the HTA ESIG over the las 10 years. The collaborations and partnerships have been truly inspiring. We continue to be an active ESIG with much to do and lots of important discussions.

Chrissie Fletcher (GSK)

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Country News

APF (Germany)

APF held its annual workshop on November 27th virtually with the topic "COVID-19 – implications to statistics" with some 100 attendees dialing in. The next annual workshop is planned for November 26th 2021.

The German statistics leaders group met virtually on November 26th with a focus on working remotely and validated R implementation.

DSBS (Denmark)

On November 26th DSBS hosted a webinar on COVID-19 and Estimands. The webinar was a great success with almost 70 attendees. Chrissie Fletcher (GSK) was the first invited speaker on the agenda and she kicked off the meeting with a presentation titled: "*What we've learned from the impact of COVID-19 to clinical trials and how estimands have helped us*". This was followed by 4 case stories presented by 4 DSBS members (representing 3 companies: Zealand Pharma, Leo Pharma, Novo Nordisk). The case stories included both reactive and proactive approached addressing COVID-19 in clinical trials. The webinar ended with a lively panel discussion between the 5 speakers. More information available on the DSBS website: Danish Society for Biopharmaceutical Statistics (dsbs.dk)

PSI (UK)

Medical Statistician Level 7 Apprenticeship Scheme.

For 18 months, Jim Saul (Covance), myself, and a trailblazer team made up of PSI statisticians and academic institutions have been working on developing a Medical Statistician Level 7 UK Government Apprenticeship, with integrated MSc Medical Statistics degree qualification. We have been working with the UK government Institute for Apprenticeships and Technical Education. With our "standard" and "end point assessment" now drafted, we hope to have entered the last stages of the process. Once we get government approval, the scheme will be open for UK companies to employ BSc graduates and enrol them onto the Medical Statistician apprenticeship scheme. The scheme runs over 36 months, with the first 30 months consisting of a taught off-the job MSc in Medical Statistics, with the apprentice keeping a portfolio of evidence documenting their on-the job medical statistician experience and learning. The last 6 months has the apprentice complete a work-based project (MSc Dissertation project), write up and Q&A sessions/interviews on their experience to date. If successful, they complete the apprenticeship and receive the MSc qualification within 3 years, alongside being in full time employment. As soon as the scheme is approved, we'll update you on next steps. However, further information about how the apprenticeship levy works, and how you can benefit as a company by recruiting an apprentice can be found at the following link: https://www.gov.uk/government/publications/apprenticeship-levy-how-it-will-work/apprenticeship-levy-how-it-will-work

Fingers crossed we'll see our first Medical Statistics apprentices starting in 2021!

Lyn Taylor (PHASTAR)

PSI 2021 Online Conference

The PSI 2021 Conference will be run online between 21 to 23 June 2021.

Regarded as the principal annual event for statisticians in the pharmaceutical industry, the 2021 PSI Conference will be taking place online. The Conference will include plenary sessions, parallel sessions and a poster display. Material will be also be available on demand plus there will be a virtual exhibitor area. Registrations will open in early 2021, along with a call for submitted oral and poster abstracts. Click here for more information

Scientific Events - 2021

The Scientific & Training committees are busy planning events in 2021 to keep you all at the forefront of great science relevant to our healthcare industry. As well as the online conference in June 2021, look out for online one-day meetings on **Immunoncology** and on **Missing data,** a webinar on **wearables** and training courses on **Data Monitoring Committees, Repeated Measures and Mixed Models,** and much more! When dates, technology and confirmed speakers are finalised these will be advertised on this eNews as well as on our website (under "Events") and in LinkedIn posts. Click here to register your interest.

MEETINGS, WEBINARS AND COURSES

EIWG Webinar: PIONEERing estimands in Clinical Research

15:00-16:30 // 09:00-10:30

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

What is the benefit of attending? Understand how to describe clinical objectives using the estimands framework, recognising the benefits of this approach.

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...

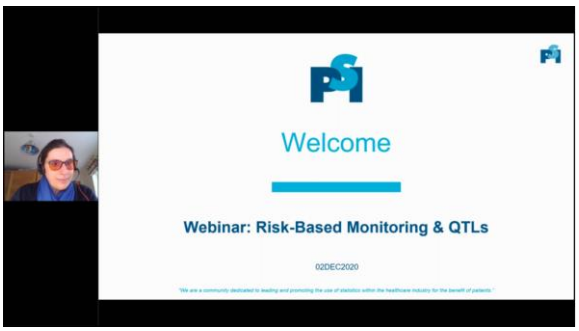
Podcasts & Webinars

Tox ESIG Webinar: Biomarkers in Toxicology
The deployment of biomarkers in drug development and diagnostics has many challenges ranging from analytical validation, in vivo study design, to the translation to human utility and financial considerations. In this video/Webinar focus is given to safety biomarkers. Statistical issues in data science that nonclinical statisticians might encounter along the way are discussed.

Watch here

Tox ESIG Webinar: Combining Sexes
The webinar provides a general introduction to the topic of combining sexes for statistical analysis in Toxicology, and guideline recommendations pertaining to this topic. For electrocardiography and jacketed external telemetry data, it will discuss scientific preferences, historical data review and statistical recommendations. For Developmental and Reproductive Toxicology endpoints, it will focus on neurobehavioral data.

Watch here



PSI Webinar: Risk Based Monitoring & QTLs
Since the introduction of ICH-E6 R2 Addendum sponsors must introduce formal Quality Risk Management and define Quality Tolerance Limits to their clinical development programs. This video is a recording of a webinar held on December 2nd 2020 that covers an introduction to those concepts, recent developments and examples of how companies are defining QTL's in practice.

Watch here

PSI Webinar: Innovative approaches in the development of paediatric medicines
Children are considered a vulnerable population. Correspondingly, developing drugs for paediatrics is associated with a range of challenges including but not limited to ethical and methodological challenges. In this webinar, representatives from different pharmaceutical companies will present innovative approaches that address the challenges of developing paediatric medicines.

Watch here

Good data visualization PART 1
Good data visualization PART 2
I'm reviewing the first page of the awesome Novartis cheat sheet on data visualization. You can also download the cheat sheet!

2 learnings from 150 episodes and an Important announcement
I still can't believe how fast things happened, and I am truly grateful for all of this. I interviewed a lot of people who have the same goal as mine – that is to build our expertise. In this episode, let's dive in the 2 learnings I had.

Alexander Schacht

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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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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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