



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

EFSPI Newsletter July 2019

In this newsletter:

[10th EFSPI Statistics Leaders Meeting](#) – key highlights

[Regulatory](#) – 4th Regulatory Statistics Workshop, regulatory guidelines for review, EFPIA/EFSPI estimand implementation working group

[Scientific](#) – reproducibility in clinical research

[Special Interest Group \(SIG\) news](#) – Decision-making SIG, Toxicology SIG

[Country news](#) – AFP (Germany), BBS (Switzerland), IBIG (Italy), PSI (UK)

[Other events](#) – 5th International Clinical Trials Methodology Conference, IBS Group sequential and Adaptive Design workshop

[Job opportunities](#) – Senior Biostatistician, Principal and Senior Biostatisticians

[The World of Statistics](#)

[Follow us on Twitter and LinkedIn](#)

[And finally...](#)

10th EFSPI Statistics Leaders Meeting



The annual EFSPI Statistics Leaders meeting took place on the 3rd and 4th July 2019 in Germany, hosted by Boehringer Ingelheim. This year, 31 statistics leaders from 25 companies met face to face for one and a half days to celebrate the 10th anniversary of EFSPI Statistics Leaders meetings. The main goals of this year's meeting were to reflect on the past EFSPI statistics leaders' topics and to continue shaping the future of the EU Statistics community based on the key lessons learned from 2010–2018. There was a key emphasis on statistical leadership.

In preparation of the meeting, all participants were asked to think about what they would like to have known early in their careers e.g. soft skills, which they felt would have helped them with advancing their development. During discussions, it became clear that to be impactful as a statistician it is necessary to combine technical strengths with soft skills, leadership and big-picture thinking. Christy Chuang-Stein and Alexander Schacht were invited as external speakers to further stimulate discussions on critical leadership skills for statisticians in the pharmaceutical industry. The outcome of their interactive presentations and round-table discussions with participants were thought-provoking and inspiring ideas on how to become an effective, bold and entrepreneurial statistician. We were reminded that change may seem scary at first, but it can also be very energizing and "If you are taking a risk, what you are really saying is, 'I believe in tomorrow and I will be part of it.'" – Linda Ellerbee.

The following hot topics were selected by participants and debated in further break-out groups: (1) What are the skill sets, besides leadership, statisticians need to have in the future?, (2) Statistics and Data Science: "The hype is over – when are statisticians needed again?", (3) Involvements of statisticians in drug discovery and early stages of clinical development, and (4) The use of external controls in regulatory decision making. All four topics were followed by a plenary feedback session resulting in an action plan for EFSPI on how EFSPI can provide support to pursue and implement the recommendations once endorsed by the EFSPI Council. Finally, our EFSPI statistics leaders got to know Boehringer Ingelheim's CUBE building, learned the Agile mindset and principles, and used the Design Thinking to create prototypes for a new EFSPI website during an Agile Experience Tour.

The 2019 EFSPI Statistics Leaders Organizing Committee thanks all who contributed to making the 10th anniversary a great success! The EFSPI statistics leaders are driven by collaboration and everyone participating strongly believes in the importance of networking in the EU Statistics community. The EU Statistics Leaders forum will continue to shape the strategy of EFSPI and motivate and inspire the current and next generations of statisticians in the pharmaceutical industry to reach their full potential. Stay tuned for upcoming EFSPI events by visiting www.efspi.org and connecting with us on LinkedIn, and Twitter at @EFSPItweet.

All presentation materials, workshop minutes and video messages from the meeting are available on the EFSPI website www.efspi.org. Enjoy seven video messages highlighting the value of EFSPI and what the EFSPI Statistics Leaders meetings have achieved:

- Video 1: Message from Chrissie Fletcher (EFSPI Communications Officer 2019)
- Video 2: Message from Hans Ulrich Burger (EFSPI President 2019)
- Video 3: Message from Stefan Driessen (Organizing Committee EFSPI Statistics Leaders Meeting 2019)
- Video 4: Message from Armin Schueler (Organizing Committee EFSPI Statistics Leaders Meeting 2019)
- Video 5: Message from Justine Rochon (Chair of EFSPI Statistics Leaders 2019) & Stefan Driessen (Organizing Committee EFSPI Statistics Leaders Meeting 2019)
- Video 6: Message from Justine Rochon (Chair of EFSPI Statistics Leaders 2019)
- Video 7: Message from Justine Rochon (Chair of EFSPI Statistics Leaders 2019) & Egbert Biesheuvel (Chair of Scientific Committee)



Armin Schueler, Hans Ulrich Burger, Justine Rochon, Chrissie Fletcher, Stefan Driessen
(Organizing Committee 10th EFSPi Statistics Leaders Meeting)

[back to top](#)

Regulatory

EFSPi is pleased to announce the 4th Regulatory Statistics Workshop taking place in Basel, Switzerland on the 23rd and 24th September 2019. The workshop will be dedicated to the discussion of opportunities and challenges of statistical topics between regulators, academics, and industry with dedicated time for interaction and discussion. The agenda includes:

- Session 1: Real-world data – beyond randomized clinical trials
- Session 2: Real-world data – applications
- Session 3: Analysis of safety in clinical trials – or how to bring a statistician out of his comfort zone
- Session 4: Estimands – are we pushing any boundaries thanks to the ICH E9 addendum?
- Session 5: Modern approaches for rare disease
- Session 6: Contributed short topics – discussions

To register for the workshop, click [here](#).

The draft ***Qualification opinion of clinically interpretable treatment effect measures based on recurrent event endpoints that allow for efficient statistical analyses*** was released for public consultation on the 19th June 2019. Click [here](#) to view the opinion. Comments can be submitted until 9 October 2019. Please send comments to Chrissie Fletcher (fletcher@amgen.com) by the end of August 2019.

The draft [Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy Guidance for Industry](#) was released for public consultation. Please send your comments to Christoph Gerlinger (Christoph.Gerlinger@Bayer.com) by end of August.

**** reminder ** EFPIA/EFSPi Estimand implementation working group** The ICH E9 working group are busy finalizing the ICH E9(R1) document with a final version being released in late summer. Many companies have, or are beginning to, develop plans to implement the new framework being introduced in the E9 addendum. An estimand implementation working group within EFPIA and EFSPi is being established to enable statisticians and clinicians to share their experiences and identify

best practices for implementing the new estimand framework. If you are leading the implementation of ICH E9(R1) and you are interested to join the EFPIA/EFSPi estimand implementation working group, please contact Chrissie Fletcher (fletcher@amgen.com). Please encourage one of your clinical colleagues to also participate with you!

[back to top](#)

Scientific

Upcoming event: ***“Reproducibility in Clinical Research”***

On **Thursday November 22nd 2019**, this scientific meeting will take place at BMS in Brussels. The purpose is to bring together speakers from industry, academia and regulatory agencies, who will address questions relating to the topic, and the role statistics (and statisticians) have in ensuring clinical research is conducted and reported in a reproducible manner.

First key speakers are announced, and a full agenda is expected end of summer. More information can be found on the [flyer](#) and the registration is open click [here](#).

The scientific committee is brainstorming on topics for the scientific events in 2020. If you have any suggestions for topics, please feel free to contact the scientific committee (chair: Egbert.biesheuvel@danone.com)

[back to top](#)

Special Interest Group (SIG) News

The **Toxicology SIG** have a series of regular FREE webinars dealing with statistical topics faced in toxicology and related fields. The presentations will run for an hour, with approximately 45 min presentation and a Q&A session in the remaining time.

The webinars planned for 2019 are:

- Tuesday 17th September 2019 – TBC
- Tuesday 10th December 2019 - TBC

All take place at 14:00 UK time. Full details will be released closer to each webinar, or contact Gareth Thomas (gareth.thomas@envigo.com) to be kept up to date on all ToxSIG activities.

The **Decision-making SIG** are organizing 2 webinars towards the end of 2019, each of 90 mins duration:

1. **“Overview and awareness about quantitative decision-making in drug development”**, end November / early December 2019
2. **“Main statistical approaches for quantitative decision-making in drug development”**, early / mid-December 2019

Further details will be available via the EFSPi (www.efspi.org) and PSI (www.psiweb.org) websites.

Country News

AFP (Germany)

The annual workshop will take place Nov 29th at Ludwigshafen/Rhein hosted by Abbvie. The main topic will be Real World Evidence (see http://www.biometrische-gesellschaft.de/fileadmin/AG_Daten/PharmazeutischeForschung/PDFs/Agenda_APF_73_Ludwigshafen_Nov_2019.pdf). The next German Statistics Leader Meeting will take place on Nov 30th 2019.

BBS (Switzerland)

BBS are holding their Summer Seminar on the 21st August 2019 in Basel with the topic of **Causal Inference in Drug Development**. Academic, Industry and Regulatory perspectives will be shared including ICH E9(R1) and the new estimand framework. A variety of case studies will be shared and there will be a panel discussion. Click [here](#) to view more details on how to register for the meeting.

BBS are holding their Autumn Seminar on the 1st November 2019 in Basel with the topic of **Predictive Modelling, Machine Learning and Causality**. The talks will present recent methodological advances and challenges as well as case studies from the pharmaceutical industry and academia. We welcome all quantitative scientists to this event which will be a great opportunity to meet with colleagues and exchange ideas on this emerging and vibrant field. Click [here](#) to view more details on how to register for the meeting.

IBIG (Italy)

The **IBIG Forum** will be held at the University of Milan-Bicocca on 10-11 October 2019. Main topics will be: randomization and blinding, study drug management, early phase clinical trials and Innovation in Statistics and next gen statistician role. Speakers from pharma industries, CROs, academia, public & private research institutes.

Scientific Committee: Vincenzo Bagnardi (University of Milan-Bicocca), Beatrice Barbetta (Rottapharm Biotech), Marco Costantini (GSK Vaccines), Arturo Lanzarotti (IBSA), Fabio Montanaro (Latis), Giulia Zigon (GSK Vaccines).

On 9 October, two pre-IBIG Forum courses are organized:

Simulation methods to estimate power and sample size in trial designs, with SAS

Instructors: Prof. Vincenzo Bagnardi, University of Milan-Bicocca
Valentino Conti, Expert Biostatistician, GSK Vaccine Institute for Global Health

Theory and practice for the creation of summary tables using ADaM domains

Instructors: Valerio Romolini, Lead Statistical Analysts, GSK Vaccines
Gabriele Di Domenico, Statistical Analyst, GSK Vaccines
Stefano Lombardi, Statistical Analyst, GSK Vaccines

The flyers for these events are available on the EFSPi website (www.efspi.org).

PSI (UK)

Register for future PSI events Register your interest now to receive updates, hear when registration opens and receive a 10% discount on the early bird rate (where applicable)!

- [Training Course: ICH Guidelines for Statisticians](#)
- [Training Course: PK Methods and Regulatory Considerations](#)
- [Training Course: Time to Event Methods](#)
- [Training Course: Bayesian analysis software](#)
- [Training Course: Adaptive design software](#)
- [Training Course: R for SAS users](#)
- [PSI One day Scientific meeting: Time-to-event and recurrent event endpoints in clinical trials](#)



A screenshot of a webinar announcement slide. The slide is titled "The RSS & PSI's Journal Club presents:" and features a blue header with the text "Survival Analysis". Below the header, it lists the date and time: "Date: 11th July 2019 Time: 4pm-6.30pm BST". The slide also lists presenters: "Peter Thall (MD Anderson)" and "Kyu-Ha Lee (Harvard)", and discussants: "Rohy Baheti (Glaxo-Genentech)" and "Aval Gandy (Imperial College London)".

[FEATURED VIDEO: PSI Webinar: The RSS & PSI's Journal Club presents: Survival Analysis](#)

The Science Media Centre

The Science Media Centre is a charity dedicated to evidence-based, responsible reporting of science in the national news media. They have an expert database of 2000+ scientists who provide quotes in response to new research to help journalists report new (and often controversial) findings accurately. Statisticians form an important group on the database. When new research appears claiming that EMF/coffee/deodorant causes CFS/cancer/depression, we often call on statisticians to help crunch the numbers and see if the claims stack up. By providing expert quotes to journalists in real time we improve the quality and reliability of reporting to the public.

If you are a statistician or epidemiologist who would like to volunteer to help the media get it right, please contact Tom Sheldon tom@sciencemediacentre.org for more information.

Pharmaceutical Statistics - Request for Volunteers

Pharmaceutical Statistics is the official journal of [Statisticians in the Pharmaceutical Industry](#) (PSI). The journal publishes papers related to [pharmaceutical statistics](#), and all articles are [peer-reviewed](#). If you are interested in reviewing potential articles for publication and/or becoming an Assistant Editor, please contact Alan Phillips at Alan.phillips@iconplc.com. Many of us have areas of expertise that the Editor in Chiefs would like to draw upon to ensure that published articles are of exceptionally high quality and relevant to the work we all do.

EFFECTIVE STATISTICIAN

2 new episodes every biostatistician should know about!

How to make the collaboration between sponsor and CRO successful

There is an endless list of things that can go wrong in sponsor-CRO relations. I'm pretty sure you have been in painful discussions about this. Have you felt a lot of frustrations on both ends?

If yes, this episode is for you. We're sharing interesting insights here as Benjamin works for a CRO and I work for the sponsor side. We will be giving you a lot of insights on what to do and what not to do, and how to make the collaboration between a sponsor and a CRO successful.

Specifically, Benjamin and I will be talking about:

- Have partnership on an equal level
- Create common expectations on quality
- Establish stable personal relationships
- Have low turnover rates
- Importance of transparency of processes
- Have a fair payment
- Invest in creating trust
- Good feedback habits
- Working towards CRO processes and SOPs
- Choosing your vendor wisely as a good choice is half the success

[Listen to this interview and share it with others, who might learn from it!](#)

How to communicate effectively by telling data stories, Interview with Kat Greenbrook

Storytelling allows businesses to better understand insight. Data visualization is a great tool to help share, or tell a story, but relies on the story being written first. Improved data communication comes from combining good visualization with a well-written narrative. At [storytelling with data](#), the goal is to rid the world of ineffective graphs and help people elegantly communicate with data. They aim to bring data to life and use it to tell a story to an audience, with a focus on simplicity and ease of interpretation. They believe everyone can inspire positive change through the stories they tell with data. [Forbes](#) also discussed the importance of telling a great data-driven story and gives a good example of how to do it. Telling a great data-driven story can be useful for both stakeholders and your

customers and can drive better decision making within an organization and also drive conversions with your customers. By using data visualization to make key observations about your customers and their wants, it can help with lead generation and customer retention. There's a lot to learn to be a good data storyteller.

[Listen to this interview to know more on how to be an effective data story teller!](#)

Enjoy listening!

Impact of AI on Clinical Development 11 September 2019, UCB, UK.

In association with PSI, UCB and Cytel are delighted to invite you to join a symposium, educating on Artificial Intelligence (AI) approaches and their impact on clinical development.

With so many recent advances in AI, it is important both for statisticians to keep up to date with the most recent methods and be involved in guiding their application to the most pressing statistical challenges. This one-day event will cover cutting edge examples of how data science and statistical sciences are intersecting, and where attendees can fit into that space. Come to learn and discuss why different approaches matter when looking at clinical development data. Click [here](#) to register.

Training Course: Improving Influence and Increasing Impact: Communication Skills for Industry Statisticians 16th September, UCB pharma, Brussels

This 1-day course will lead participants through steps to focus on improving the key skills of making impactful verbal and written communications. It is designed to be interactive and lively, with a focus on the statistician rather than the statistics and will include workshops to practise the skills and behaviours discussed. Topics include: preparing posters, tips for written reports/abstracts, preparing and delivering presentations, effective team communication and key roles, and delivering negative messages to teams with positive impact. Click [here](#) to register.

[back to top](#)

Other events

5th International Clinical Trials Methodology Conference (ICTMC) : 6th-9th October 2019 in Brighton

This event promises to be a unique opportunity for those working in clinical trials to meet and discuss the current issues within trials and trials methodology. The event will showcase the very latest in trials methodology research and offer plenty of valuable opportunities for networking. The Conference will also mark 10 years since the Network of Hubs for Trials Methodology Research began in 2009.

Following a record number of abstract submissions, we hope to announce the programme early next month. The **Early Registration reduced rate deadline is 8th July**. Please [see the ICTMC](#)

[webpage here](#) for all the details.

Group Sequential and Adaptive Clinical Trial Designs

The German Region of the International Biometric Society (IBS) is holding a summer school on Group sequential and adaptive clinical trial designs, 17-19 October 2019 in PfalzAkademie, Lambrecht, Germany. This summer school introduces group sequential and adaptive designs, and also covers advanced topics. The theory will be illustrated with case studies from the pharmaceutical industry. Each module of this course includes a computer practical. We will use the R software package rpact (R Package for Adaptive Clinical Trials, <https://www.rpact.com/>), a validated, comprehensive and freely available package for the design, simulation and analysis of group sequential and adaptive trials. More information can be found on the [EFSPI website](#). Please register through this [link](#).

[back to top](#)

Job Opportunities

There is an opportunity for [Senior Biostatistician, Principal and Senior Biostatisticians](#). 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](#)



The World of Statistics

The World of Statistics is comprised of 2,360 organisations across the globe. Participating organizations in The World of Statistics include national and international professional statistical societies, colleges and universities, primary and secondary schools, businesses, government statistical agencies, and research institutes. You can view the current participant and country lists involved in the World of Statistics by going to The World of Statistics website <http://www.worldofstatistics.org/>.

[back to top](#)

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.

[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.

[back to top](#)

Chrissie Fletcher
EFSPI Communications Officer

