

EFSPi Newsletter

JULY-AUGUST 2022

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WELCOME



A warm welcome to the "Summer Edition" of our EFSPi newsletter!

After receiving lots of feedback from you, I decided to enjoy my vacation, go offline and then come back with a single, energising newsletter combining news over summer 2022 with a special focus on our 13th EFSPi Statistics Leaders Meeting and the European Special Interest Groups (ESIGs).

In addition, the idea of a special "summer edition" launching a new format of the EFSPi newsletter sounded like music to my ears. My sincere thanks go to Stefan Englert who offered a new branding proposal and delivered a fantastic solution. And... Here it comes: the new look of our newsletter!

Enjoy the reading and let me know how you liked this edition. Please also contact me if you have anything you would like to contribute to our newsletters and the EFSPi community.

Stay healthy, stay safe!

Justine Rochon
EFSPi President and
Editor of EFSPi Newsletters



EFSPi COUNCIL NEWS

Let's set the scene!

As you might know, the European Federation of Statisticians in the Pharmaceutical Industry (EFSPi), is open to constituted groups of statisticians. So, there is no individual membership. Eligibility for membership is open to one national group per country placing a major emphasis on scientific and technical activities directed at statisticians who are working in the pharmaceutical industry. For now, there

are 10 [EFSPi member groups](#). Thus, 10 European countries are represented in the EFSPi Council. The Council governs the direction and long-term policy of the federation. It consists of at least one delegate from each of the countries represented through the full member groups. As a rule, representation of a country is assumed to be covered by two delegates, see [EFSPi Council Members](#).

The EFSPi Council meets quarterly

The first three meetings in 2022 took place virtually. Our next meeting is coming very soon, and the plan is to finally meet in person on 16th September, the day after the EFSPi Regulatory Statistics Workshop in Basel/Switzerland.

Stay tuned to hear more soon!

Please join me in welcoming Alun Bedding as new EFSPI Council member!

Alun Bedding is replacing Steve Jones in the EFSPI Council for UK. We thank Steve for his commitment and contributions to EFSPI and wish him all the best.



Alun Bedding is the Global Head of Methods, Collaboration and Outreach in the Data and Statistical Sciences Department at Roche, based in the UK. He has worked in the pharmaceutical industry for 33 years and is currently on his third time on the PSI Board. Alun is a DIA Innovative Design Working Group and Bayesian Methods Working Group member. He is also a member of the UK Medical Research Council Experimental Medicine funding panel and the Great Ormond Street Hospital funding board. Alun is passionate about collaborations with academia and is currently the industry supervisor for two PhD students at Lancaster. In connection with this, Alun will be driving the EFSPI outreach stream, focusing on academia.

Enjoy a deeper dive into the history of EFSPI!

Alun was on the PSI Main Committee as the Secretary when EFSPI was formed in 1992. So, even though the [history page](#) on the EFSPI website is excellent, he contacted Alec Vardy, the first EFSPI President about the formation. The following are extracts from what Alec told Alun:

Whilst Alec was working at Pfizer in the UK from 1985–1988, he became very active in PSI. When he went back to The Netherlands in the middle of 1988, the "isolation" of statisticians working in the small number of companies there became painfully apparent. There was an annual conference for statisticians in Lausanne/Switzerland around that time and on attending that it became clear that industry statisticians across Europe were dealing with similar issues. So, with the full support of PSI and his manager at Duphar (now Abbott), he contacted leading members of the individual country organisations. He even paid a visit to meetings of the Swedish and German groups to provide information about PSI and its activities, with the presentations being very well received.

A total of six national groups were ultimately identified (the founding members), and they were all invited to Weesp in November 1990. There was tremendous enthusiasm for collaboration, and EFSPI was formed. The rest, as they say, is history. They agreed to meet every six months, and the PSI Board created a committee liaison function.

After handing over the PSI Chair at the end of 1991, and joining a CRO in 1992, Alec was no longer involved in EFSPI meetings or activities. To counteract the 'withdrawal symptoms', a few people working in The Netherlands decided to get together and connect statisticians and data managers within the country, from which PSDM was born (and subsequently became an EFSPI member).

Alec goes on to say that looking at the EFSPI website, it's amazing to see what has grown out of the original seed that was planted back in 1990.

And there is so much more to happen as we at the EFSPI Council have not only committed to focus on ensuring business continuity but also to enhance our visibility (including more presence on LinkedIn, a new look for our newsletter, and a new EFSPI website coming soon), and to further transform EFSPI into a federation that makes a difference today and into the future. If you want to learn more about EFSPI, please visit our [EFSPI website](#) and follow our official [EFSPI LinkedIn page](#), engage with us by reacting to our posts, commenting and sharing the information with your networks.



EFSPI REGULATORY STATISTICS WORKSHOP

The countdown is on! Only a few more days until the 7th EFSPI Regulatory Statistics Workshop will take place on September 14–15, 2022 as a hybrid meeting at [the Biozentrum Basel](#).

The registration is closing soon! 5 September for F2F and 13 September for virtual attendance!

The program includes eminent speakers from several European Health Authorities, FDA, academia, and industry, and will discuss opportunities and challenges in drug development. Planned topics are:

- Introductory Keynotes on “What happened in the last two years in regulatory and HTA landscape?”
- Postbaseline subpopulation analyses: Known to be improper, but frequently done. Can we fix them?
- Regulators and HTA bodies for new designs in Europe – how to deal with different priorities, especially for new design types?
- Generalizability and external validity: How to generate evidence about a treatment effect?
- Role of statistics / quantitative science in regulatory decision-making

Please follow below links for further details, including program, registration costs and payment, as well as frequently asked questions: [Program](#), [Registration](#), [FAQ](#).

13th EFSPI Statistics Leaders Meeting 6th and 7th July 2022

Basel Switzerland co-hosted by Novartis and Roche

The 13th Annual EFSPI Statistics Leaders Meeting was jointly hosted by Novartis and Roche.

Emmanuel Zuber (Novartis) and Hans Ulrich Burger (Roche) made it easy for the visitors to fall in love with Basel and to become curious about the history of the two companies based in the same city. The ‘ping-pong dialogue’ between Emmanuel and Uli was not only informative but also super entertaining.

Day 1 of our 13th EFSPI Statistics Leaders Meeting started with a warm welcome from the organising committee and an amazing tour at the Novartis Pavilion, a new learning, event, and exhibition space for Basel that explores the big questions around healthcare – a space where everyone can learn about, engage with, and be inspired by the wonders of medicine!

The EFSPI Statistics Leaders were then asked in an icebreaker session to put cards with some key events and innovations in healthcare on correct places ranging from the 14th Century through to the 21st Century. This was a great collaborative, educational and fun exercise!

The first breakout session was dedicated to the question: How can EFSPI advance its networking and collaborations with other groups? The objectives were to identify opportunities for EFSPI to strengthen its links with other professional and industry groups and to identify how EFSPI can help statisticians build networks and contribute to professional/industry activities. In this session, the audience learned more about the Biometrics Statistics Leaders Consortium (BSLC) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) from two invited speakers, Erik Pulkstenis (representing BSLC) and Silvia Garcia (representing EFPIA). After their talks, the discussion continued at round tables and each round table presented some tangible solutions for EFSPI to consider pursuing and suggested partnerships to prioritise.

An invited motivational speaker, Stanley Shaw from Harvard Medical School, closed Day 1 of the meeting with an excellent presentation on “Perspectives on Innovative Data Science Leadership in the Life Sciences Industry” which gave the EFSPI Leaders some great food for thought on what is really needed to be ready for the future. Stan’s ideas triggered a lively dialogue that lasted for the rest of the evening.



13th EFSPi Statistics Leaders Meeting 6th and 7th July 2022

Day 2 began with the second breakout session focussing on the development of NextGen Statisticians. The objective was to discuss what EFSPi can do to support the next generation of statisticians and statistical leaders, so everyone is equipped with skills required for modern R&D. Invited speakers were 3 statisticians from Novartis and Roche, Kristina Weber, Alex Ocampo and Evgeny Degtyarev, who shared their career journeys to date. What did we learn from them? First of all, we learned that statisticians working in the pharmaceutical industry want to be considered as drug developers and be key drivers of data-driven decisions. We heard about patient-centric statistics and that many new statisticians are entering the Pharmaceutical Industry because they want to make a difference in the lives of people. At the same time, statisticians have a high need for continued education with a focus not just on technical skills but also on 'soft skills' that are not soft at all (e.g., cross-functional leadership, negotiation and influencing skills, strategic thinking, storytelling, and understanding of cultural differences). In addition, feedback was provided on: post-pandemic ways of working and being able to achieve work-life balance; creating a diverse

and inclusive workplace where all statisticians can thrive; ensuring adequate female representation at all organisational levels; being able to gain a good understanding of different aspects of drug development; and enabling open and transparent discussion of career development opportunities within and outside of statistics. Kristina, Alex and Evgeny were thanked for sharing their perspectives with the EFSPi Leaders. There is simply no better way to get input from the 'NextGen' than connecting with and actively listening to them! EFSPi is committed to shape and bridge today's and tomorrow's statisticians working in the pharmaceutical industry. You will for sure hear more about this important topic from us.

The final session on Day 2 involved a panel discussion focused on the question "How can statisticians up their game to maximise their impact and meet the demands of modern drug development?". The objectives of this session were twofold

- 1) to review the challenges and opportunities for statisticians to lead, influence and maximise their impact in the evolving drug development data sciences environment
- 2) to identify areas for change in mindset, behaviors, skills, and organisational structure and strategy which we need to work on as leaders.



The EFSPi leaders were pleased to receive an inspiring video message from Eric Genevois-Marlin, Head of R&D Data and Data Sciences at Sanofi. Then, Chris Holmes, Professor of Biostatistics at the University of Oxford & The Alan Turing Institute delivered a brilliant speech about “Biostatistics into the Future”. Despite the fact that “Prediction is very difficult, especially if it's about the future.” (Niels Bohr), we learned from Chris not only about all the challenges that lurk around the corner but also about all the opportunities that open up for statisticians.

Here are a few examples of what the future may bring to statistics:

- There will be a shift towards the well-being, early intervention, preventative medicine and balancing multiple long-term conditions.
- Simulation will increasingly be used as an inference tool. We will move towards real-world continuous (Bayesian) adaptive clinical trials and causal inference will be mainstream.
- The ability to measure outcomes is no longer a bottleneck, rather the challenge comes from how to capture, store, assimilate, and make sense of real-time data from multiple sources.

For leaders there is an overarching challenge (and opportunity!) to create an environment and culture for analytic teams that can keep pace with all these developments.

2022 Steering Committee:

Emmanuel Zuber, VP, Global Biostatistics Head, Hematology Development Unit (Novartis), **Hans Ulrich Burger**, Data and Statistical Sciences Global Head Neurosciences (Roche), **Tina Christiansen**, CVP Biostatistics (Novo Nordisk), **Justine Rochon**, SVP Global Biostatistics and Data Sciences (Boehringer Ingelheim), **Christine Fletcher**, VP Specialty and Primary Care Statistics, Biostatistics (GSK), **Bibiana Blatna**, Administrative Professional (Novartis), **Tricia Byers**, Senior Administrator (GSK)

The leaders were intrigued by Chris on his views about the self-reflective question: “Biostatistics – death or glory?” where Chris feels statistics will remain a core discipline within biomedical data science. However, he noted it is not implausible that highly repetitive analyses, such as those specified in Statistical Analyses Plans for Randomised Controlled Trials, will become fully automated although he was quick to clarify “We’re way off automated statisticians”. On the positive side, Chris highlighted that statisticians have strong self-selection for a feel (“a good nose”) for data. Much of the art of applied statistics and the skills of a trained statistician involve factors that cannot be captured by algorithms. Statistics provides the formal language and rigour for the communication and interpretation of scientific findings from data. The fundamental properties of sampling variability don’t go away just because we use AI. They become even more important. Finally, Chris highlighted that statisticians are the guardians of reproducible research and stability of findings – accurate uncertainty quantification. These are essential skills with increasing importance. Therefore, Chris’ advice is to create agile teams with a blend of skills, shared appreciation of cultures and domain strengths, and this has the potential for a super exciting future!

As you can imagine, these predictions triggered an exciting debate that lasted until the end of the meeting. The EFSPi leaders left the Novartis campus in Basel full of energy and strength that they will pass on to their people and the entire EFSPi community.

During the 2-day meeting, the EFSPi Statistics leaders were able to enjoy the architecture and fine arts at the Novartis campus (with the two Roche towers visible in the background!). As stated in the Visitor’s Map: “Exceptional performance needs an exceptional environment [...] new ideas come from unexpected impulses [...] for this reason, artworks form an important part of the campus: they are intended to inspire, sharpen perception and awaken a feeling for connections and new perspectives.” Thanks to Novartis and Roche led by Emmanuel and Uli for hosting the 2022 EFSPi Statistics Leaders in 2022 and to the steering committee for an inspiring meeting!

ESIG News

Our European Special Interest Groups (ESIGs), jointly sponsored by EFSPi and PSI, are playing a key role and foster connections across disciplines, industry, academia and countries/regions.



"What a fantastic PSI Conference in Gothenburg this year! It was so good that it even made up for the baggage reclaim experience at Heathrow T3 on return. Like many others, I could have done without the COVID, but at long last, my cough has gone, and the ABBA tribute band was wonderful (I confess at this point to being a huge fan but aren't we all?)."

The Scientific Committee put together a great program, and as PSI Director for our Special Interest Groups it was wonderful to see the extensive contribution from our ESIGs, which are jointly overseen with EFSPi, represented by Emmanuel Pham. More than half of our 20 ESIGs organised or contributed to conference sessions. If my tally is correct, within main sessions we had contributions from Launch & Lifecycle, Data Science, Subgroups, Historical Data, Benefit Risk, COVID, RWD, Oncology Estimands, Data Sharing, AIMS and Visualisation, with posters from the newly re-launched Biomarkers ESIG and Oncology Estimands.

It was great to be able to meet so many colleagues for the first time, in some cases after several years of correspondence, and I'm looking forward to getting back out on the road in support of future events. And the ESIGs are not done yet this year, look out for upcoming events from Biomarkers, Launch & Lifecycle, Pre-Clinical, Visualisation and more! My thanks to everyone across the ESIG community for your contributions to the conference this year."

Do you want to contribute to our ESIGs? For the names and contact details of our ESIG leads, please see our [ESIG Lead Contact Page](#).

Do you want to become our ESIG of the month? Then please contact [Emmanuel Pham](#) (EFSPi SIG liaison) or [Adam Crisp](#) (PSI Board SIG liaison lead) to be featured in one of our next newsletters.

ESIG OF THE MONTH

The Pre-Clinical Special Interest Group



The Pre-Clinical ESIG was formed originally as Toxicology Special Interest Group in 2006. Since then, we have grown to have around 50 affiliates; these are mostly statisticians working across industry (pharma and CRO) and academia.

The core team members meet once a month and our focus is to share learnings, discuss challenges, explore opportunities, and learn from each other's experiences. We also work together to organise webinars and workshops. Typically, we have three webinars and one workshop every year. This year we are delighted to be holding our first and virtual workshop in September, that will include a course on the applications of Bayesian Statistics in a pre-clinical setting.

For more details on the webinars and workshops we have coming up please check out our [webpage](#).



AIMS ESIG



The Applications and Implementation of Methodologies in Statistics (AIMS) ESIG's objective is to support and contribute to working groups researching the use of R in Pharma/Biotech/healthcare research (click [here](#) to learn more).

Closely linked to the R Validation Hub, we have representatives from PAREXEL, PPD, GSK, PHASTAR, Eli-Lilly, Veristat, Floating point statistics, J&J, Roche, Incyte and Boehringer Ingelheim. Our team members, collaborate with various working groups, such as R validation hub (White Paper documenting the framework to assess package risk, riskmetric package and R shiny app <https://www.pharmar.org/>), pharmaverse (Suite of R packages aiding SDTM, ADaM & TFL creation <https://pharmaverse.org/>), and other R Consortium working groups such as RTRS (looking at table creation), R Submissions Pilot (test submission in R to the FDA), and Clinical Statistical Reporting in a Multilingual World (CSRMW)/PhUSE initiative (looking at differences in statistical analysis results between different programming languages [in SAS and R]). Our efforts help to ensure groups don't work in isolation, spreading knowledge of each groups work with the wider PSI and EFSPi community, with the hope this avoids duplication of effort and makes teams more efficient with the resources they have available.

In the PSI 2022 session, AIMS ESIG chair Lyn Taylor (PAREXEL) gave an overview of the various collaborations working towards a shared mission to enable the use of R in a regulatory setting, where the output may be used in submissions to regulatory agencies.

Following the overview, Matt Neilson (PHASTAR) presented on applying the riskmetrics package in practice in order to develop an approved package controlled R platform, and Christina Fillmore (GSK) presented on GSK's journey implementing an R platform for regulatory use, including challenges such as upskilling the workforce and rolling out a new ecosystem.

The session concluded with Min-Hua Jen (Eli Lilly) presenting a summary of the CSRMW's plans for a White Paper, framework and public repository for collating differences between SAS and R. Min-Hua also presented work conducted as part of the CSRMW survival analysis working group through collaboration with Mia Qi (Janssen R&D). It highlighted discrepancies between SAS and R, with regards to the default options, as well as different estimates under specific data scenarios for the median survival estimate, the survival estimates and confidence intervals for specified time points, and for log-rank test p-value for pairwise comparisons.

Data Visualisation ESIG



For many years one session at the PSI conference had been dedicated to data visualisation. Interestingly, a core group of data visualisation enthusiasts turned up to nearly each of these sessions. And this core group was the origin of the visualisation special interest group (VIS ESIG), which formed just before the pandemic hit (click [here](#) to learn more).

At PSI 2022, it was the first time the VIS ESIG could organise an in-person session at a conference. Unfortunately, due to ongoing travel restrictions many ESIG members could not join the conference but were at least very actively involved in the preparation work. This resulted in 4 high-quality presentations covering various aspects of data visualisation given by Alexander Schacht, Steve Mallet and Bodo Kirsch.

Many of these presentations included examples from the flag ship event of the VIS ESIG – the Wonderful Wednesday Webinar (WWW) series. This monthly challenge (see more about WWW [here](#)) runs now for over 2 years and has created a treasure of data visualisation examples which highlight different aspects of data visualisation principles and approaches (check out the VIS ESIG [blog](#) to explore this treasure). All these use typical data sets and their challenges from clinical trials and other data sources we as statisticians in pharma work with.



The VIS ESIG session – which for the first time happened in the largest room – ended with a panel discussion including many questions from the audience. The large and active attendance underpins the increasing importance of data visualisation as a critical methodological area for statisticians in pharma. The chair of the VIS ESIG – Bodo Kirsch – summarised this in his ending remarks where he highlighted the progress we have made as a community. We see a strong improvement in the use of great data visualisations across all presentations and posters at the conference.

If you would like to join the VIS ESIG to network with others interested in this topic and to learn more about data visualisation, please contact [Bodo Kirsch](#).

focus on robust mixture priors. She was followed by Julia Niewczas and Oliver Sailer who shared examples of trials where these methods are used to borrow information from external control groups, including a recent study in Idiopathic Pulmonary Fibrosis. Gaëlle Saint-Hilary completed the session by providing a detailed recipe to evaluate and present design characteristics to justify the use of BDB.

In the second session the participants turned their knowledge into practice. Simon Wandel and Aaron Dane presented a case study where a sponsor plans to augment a control arm with historical data. The participants then formed teams to propose and discuss a regulatory submission strategy for this example. The sessions were very well attended, and the ESIG members received great feedback for future work.

Historical Data ESIG



Many approaches for designing and analysing clinical trials using historical (or other external study) data have been proposed in the recent past. However, there are still many open questions concerning the role

which clinical trials that use such data can have in drug development. The three most important questions are:

1. What is the state of the art regarding approaches to incorporate historical data into the formal design and analysis of clinical trials?
2. Which statistical methods should we use to make historical and current data comparable?
3. What are the regulatory requirements necessary for the acceptance of historical data in drug approval?

The scope of the Historical Data ESIG is to provide some answers to the above questions through a variety of activities (click [here](#) to learn more about the ESIG).

At PSI 2022, the Historical Data ESIG presented two sessions on “A framework for evaluation of Bayesian Dynamic Borrowing (BDB) designs in pivotal studies”. Nicky Best opened the first session with an overview of BDB methods with a

Subgroup Analysis ESIG



Subgroup analysis is routinely conducted in drug development, in various settings. One key aspect is the regulatory requirement to demonstrate consistency of treatment effect across a pre-defined set of subgroups. Another aspect is subgroup selection, where the aim is to estimate the effect in the most promising subpopulation.

The ESIG aims to provide as much guidance and clarity as possible on inherent issues and approaches to the problems encountered in these areas, and to promote cross industry research collaborations. Since a White Paper in 2018, this ESIG is not only devoted to questions related to fixed (pre-specified) sets of subgroups, but also to the developments in personalised medicine, where lots of progress has been made in recent years on data-driven subgroup-detection/ML methodologies (click [here](#) to learn more).

The topic at PSI 2022 was “Practical and Theoretical aspects of Assessing Treatment Effect Heterogeneity”, and Tobias Muetze was chairing. The presenters were David Svensson (ESIG lead), Björn Bornkamp and Stefan Franzen. The first talk covered recent advances in the Individual Treatment Effect research area, and (in particular) so-called SHAPs were introduced. This is a rather novel variable importance concept that quickly has become popular in the broader data science area, but less so for subgroup/CATE settings. Some benchmarking of this was included via various popular machine learning based approaches for discovering predictive biomarkers.



The second talk covered an interesting data challenge from Novartis, where many different analysis teams across the company aimed to predict a novel subgroup and the corresponding (hopefully enhanced) treatment effect. The training data was four PhIII trials, and predictions from each team evaluated against actual results from the later PhIII trial. Various aspects of this was covered, e.g., metrics used, how estimates distributed, how the complexity of the subgroup definitions varied, and what methods tended to appear among the performing predictions. The last talk showcased a practical example of assessing treatment effect heterogeneity using modern approaches on observational data (diabetes/HbA1C example). Apart from being generally a fun talk to listen to, it also was educational in its discussions of assumptions, limitations and details behind forest-based approaches.

Biomarkers ESIG

Earlier this year, we relaunched the Biomarkers ESIG.



At PSI 2022, we had the opportunity to present our “Why? What? Who?” during a [poster presentation](#). We were grateful for the received feedback and we were more than happy to welcome new members.

Meeting minutes can be found on the [PSI homepage](#) and on our [LinkedIn channel](#).

We are very thankful for the great support from PSI, EFSPi and from members of the former ESIG, which were all very pleased to see that the Biomarkers ESIG was brought back to life.

What is next? We plan a webinar in November 2022 around our priority topics for 2022:

- Machine Learning for Biomarker Analysis
- Biomarkers-based designs
- Building a data repository of publicly available biomarker data

We also look forward to joint sessions with the [Subgroup ESIG](#) and with the [Visualisation ESIG](#).

Interested in joining the Biomarkers ESIG? Then contact [Guillaume Desachy](#) or [Nicole Krämer](#).

HTA ESIG

Final comments on the August EUnetHTA21 deliverables have now been submitted and are able to view.



The next round of review we will facilitate is on the October deliverables available on 3rd October. Please see our Health Technology Assessment (HTA) ESIG [webpage](#) for further details.

The HTA ESIG is hosting a webinar! “**Statistics in EU HTA - PICOs, Estimands & More**”. Registration is now open and free for all to attend! For more details click [here](#).



LOCAL ASSOCIATION OF THE MONTH

The Belgium section of EFSPi is embedded in the Royal Statistical Society of Belgium

The Society was established in 1937. In 2017, it received royal favour of the King Philippe of Belgium and became the Royal Statistical Society of Belgium (RSSB). The RSSB brings together statisticians from Belgium working across statistical disciplines and institutions. The scope of RSSB is to contribute to scientific progress in statistics by promoting co-operation between Belgian statisticians and to help the public to get better understanding of the place of statistics in the modern world. This is reflected in the board composition which unifies representatives from nine universities, the private sector and from governmental organisations across the language regions.

For local events in the area of biometrics or medical statistics, an agreement has been made to closely collaborate with the Belgian chapter of the International Biometric Society (which is called the [Quetelet Society](#)). Every year, at the annual meeting of the Belgian Statistical Society there is at least one targeted session in the field of biostatistics. Furthermore, the Belgian section of EFSPi has been organising various one-day events in collaboration with EFSPi.

The group is always looking for volunteers to join in organising events. So do not hesitate to reach out in case you are interested.

More information about the RSSB can be found [here](#).

An Vandebosch, Belgian representative in the EFSPi Council

APF (Germany)

The German region (APF) is planning their yearly meeting ("Herbstworkshop") on Friday, November 25th in Berlin (hosted by Cytel). Suggestions for topics and volunteers for presentations are highly welcomed and can be send to [Frank Langer](#). One day before, on November 24th, there will be a senior face-to-face meeting for our Academia-meets-Industry initiative (Organisers in 2022 are: Jan Beyersmann (Ulm University), Cornelia Kunz (Boehringer Ingelheim), Kathrin Stucke-Straub (THU Ulm)). This meeting is an opportunity to network in particular across academia and industry regarding statistical-methodological topics and partnerships.



OTHER COUNTRY NEWS

SFdS (France)



The 9th Statistics and Biopharmacy (SnB) Conference organised by the Statistics and Biopharmacy group of the SFdS (French Society of Statistics) will be held in Paris September 19–21, 2022. It is a unique event, usually organised every four years, integrating multiple perspectives on innovative applied statistical research for the drug development and an excellent opportunity to meet colleagues from academia, regulatory agencies, and pharmaceutical companies. More information on the SnB 2022 program can be found [here](#).

SAVE THE DATE FOR THE NEXT PSI CONFERENCE!



PSI (UK)

We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients

MEETINGS, WEBINARS AND COURSES:

21 September 2022:

[PSI Pre Clinical SIG Workshop 2022](#)

27 September 2022:

[PSI Training Course: An Interactive Introduction to Agile Ways of Working](#)

Wonderful Wednesday 28: Pediatric growth modelling

In pediatric drug development special interest is in an adverse impact on the growth of the children. Zak Skrivanek presents examples to visually explore effects on growth. All visualisations are available on the Wonderful Wednesday blog. [Watch here!](#)

Pre-Clinical ESIG Webinar: Assay Qualification by Linear Mixed Model: Confidence, Prediction & Tolerance Intervals

Bernard Francq discusses the need for analytical methods to deliver unbiased and precise results. He talks in detail about confidence, prediction and tolerance intervals in linear mixed models and the interpretation of statistical results. [Watch here!](#)

The Effective Statistician Podcast

Listen to these episodes and share them with your friends and colleagues who might learn from it.

Alexander Schacht [Listen here!](#)

NON-PSI EVENTS:



RSS 2022

International Conference

Date: 12–15 September 2022

Location: Aberdeen, UK



JOB OPPORTUNITIES

Nowadays, job opportunities for statisticians and other data scientists are excellent!

For information on how to submit recruitment adverts, please visit the [job postings](#) on our EFSPi website. 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.



AND FINALLY...

We value your feedback, so let us know what you think! What should we keep, start or even stop doing when creating the EFSPi newsletters?

We would also like to learn from you how we can further improve our EFSPi communication and branding.

Send your feedback to

[Justine Rochon](#) and [Randi Grøn](#).

To add your email address to the EFSPi mailing list, click on "Sign up to our newsletter" on our landing [page](#). To view all newsletters please see the "[News](#)" area on the EFSPi website.

Finally, you are cordially invited to join our (closed) EFSPi group by requesting access to the [EFSPi LinkedIn Group](#) in order to exchange even more within our EFSPi community.