

EFSPI Newsletter May 2022

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Welcome

A warm welcome to the May newsletter from EFSPI!



Another month flies by, and although the spring and ‘almost summer’ season is upon us, the situation in Europe continues to be serious. Hopefully the EFSPI newsletter might help here a bit and serve you with some interesting information on WHAT we are doing and WHY.

This month was a busy but great one for EFSPI as we had not only taken care of our core business but also worked hard on enhancing our visibility and bringing our federation to the next level! Learn about our ambition to create an EFSPI training academy, get to know our ESIG as well as our local association of the month, and more.

Enjoy the reading and please help us to spread the word! Follow our official [EFSPI LinkedIn page](#), engage with us by reacting to our posts, commenting or sharing the information with your networks. Your contribution to our EFSPI community matters, even with the little things.

Stay well, stay safe wherever you are!

Justine Rochon, EFSPI President and Editor of EFSPI Newsletters

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EFSPI Council news

International Clinical Trials Day



On 20th May, we celebrated the International Clinical Trials Day: A day chosen to create awareness for and recognise those working on clinical trials.

The date has been selected to commemorate one of the very first clinical trials, initiated on 20th May 1747, by James Lind (1716–1794) whilst investigating a promising cure for scurvy. While the description of the scurvy trial refers to 12 participants, the design, conduct and analysis of clinical trials to date has become increasingly complex for a variety of reasons.

As statisticians working on clinical trials in the pharmaceutical industry, we witness every day those challenges: the definition of the treatment effect and how to quantify it is complicated through the potential occurrence of events during conduct of clinical trials. Missed participant visits, lack of adherence, individual switches in treatment to alternative medication due to lack of efficacy or tolerability issues prevent observing the outcome under the treatment as it was intended for.

While quantitative decision making is an integral part of clinical trials the quality of the analysis depends on the quality of the data. So as important to defining the treatment effect and data to be captured is the measurement of the data itself. Caregivers, investigators, and all employees in clinical trials facilities are working on a daily basis to fulfil and deliver the data to address the objectives outlined in the clinical trial study protocol. Their role is instrumental in the process, and sometimes to be conducted in difficult circumstances. For example, consider the recent pandemic in which the conduct was convoluted due to various sanitary measures but nevertheless continued to deliver on the promise of vaccines and therapeutics.

So please join us in sharing your appreciation for those working every day on the conduct of clinical trials, recognising their efforts, and underscoring their important role therein.

An Vandebosch on behalf of the EFSPI Council

EFSPI Statistics Leaders Meeting

We are excited with the upcoming EFSPI Statistics Leaders meeting taking place on the 6th and 7th July in Basel, Switzerland hosted by Novartis and Roche. Thirty-six leaders are currently planning to attend the meeting this year, with the majority attending in person. The meeting will include: An interactive team building session, a keynote speaker on what the future might look like and what opportunities that lie ahead, two breakout sessions (on how EFSPI can advance its networking and collaborations with other groups, including two guests to share their experiences, and how to develop NextGen Statisticians, including three guests who will share their career journeys), a panel session on how statisticians can maximise their input and meet the demands of modern development, including three invited speakers and their perspectives of working with statisticians, and finally a walking tour and break times to socialise with each other.

A summary of the meeting and all the meeting materials will be made available to everyone after the meeting via the EFSPI website.

Chrissie Fletcher, Lead for the EFSPI Statistics Leaders Meetings on behalf of the organising committee: Emmanuel Zuber (Novartis), Hans Ulrich Burger (Roche), Tina Christiansen (Novo Nordisk), Justine Rochon (Boehringer Ingelheim) and Chrissie Fletcher (GSK)

EFSPI Training Academy



EFSPi has the ambition to create a Training Academy which aims to provide tailor-made, targeted, high-quality training in line with the [constitutional objectives of EFSPi](#). All kind of trainings, technical and non-technical, on-line and classroom trainings are in scope.

Activities of the academy will be based on local EFSPi member organisation activities but ultimately may go beyond.

With this ambition in mind, the first meeting of this new initiative took place on 29th April with representatives of all national organisations.

Although the ambitions are high, we decided to start realistic and step-by-step. As a first step we decided to create and share an overview of all trainings organised by the local organisations in the previous years but also planned or intended for the next year(s).



Share training across member organisations



WHY is sharing local training beneficial:

Whom	Why
✓ Individual statistician*	Cheaper and therefore higher likelihood to attend
✓ National Organisation	Less effort to organise local training for members
✓ Trainer	Higher return on investment. Repeating is very cost efficient
✓ EFSPi	Reach much broader group of people
✓ Coordinator (you)	Networking opportunity
✓ Climate	Less travelling, only the trainer
✓ Attendees	Way more interaction than online, great local networking

* Individual consultants, statisticians from small companies, and ↑# statisticians from large companies

If you want to know more about this new initiative or have any questions, please feel free to contact [Egbert Biesheuvel](#). The next meeting will take place mid of June 2022, so stay tuned!

Egbert Biesheuvel and Hans Ulrich Burger on behalf of the EFSPi Council

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ESIG of the month

The Oncology Estimand Group is our ESIG of the month!

The draft addendum of the ICH E9 guideline on Statistical Principles for Clinical Trials was released in August 2017. An estimand framework was born...



The estimand framework aims at aligning trial objectives and statistical analyses by demanding a precise definition of the inferential quantity of interest, the estimand. The need to amend E9 with a discussion on estimands grew out of the realisation of an apparent lack of alignment between the objectives stated in a clinical trial protocol and the accompanying quantification and interpretation of the treatment effect reported in a regulatory submission.

While the estimand framework has been developed with different clinical trial settings and endpoints in mind, the examples discussed in publications, at scientific meetings, and in the addendum have largely focused on symptomatic studies and continuous, longitudinal endpoints. However, in oncology primary endpoints in clinical trials are typically of the time-to-event type (such as overall, progression-free, or event-free survival). For these endpoints, there are still open questions concerning endpoint definition, data collection, analysis methodology, interpretation, and use in drug development.

In February 2018, Evgeny Degtyarev and Kaspar Rufibach started an informal working group to discuss how to implement this draft addendum in oncological clinical trials. In November 2018, the working group was established more formally by EFSPi as European Special Interest Group “Estimands in Oncology”, sponsored by [EFSPi](#) and [PSI](#) and in June 2019 the ASA Biopharmaceutical Section has granted the official status as [ASA Scientific Working Group](#).

In December 2019, the final version of the [ICH E9 Estimand Addendum](#) was published.

The working group aims at bringing together statisticians from industry, regulators, and academia to ensure common understanding and consistent definitions for key estimands in oncology across and share experiences, intercurrent events, and the used sensitivity analyses. Another purpose of the group is to maintain a network of oncology statisticians globally that work together in turning challenges into opportunities, ideally in collaboration with academia and regulatory colleagues. As an example, the intercontinental team spirit allowed to come up with a rapid response to COVID-19 pandemic: a [sliddeck](#) 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. In addition, we hold regular TCs with colleagues from eight regulatory agencies globally, to share our work and seek their feedback.

If you want to learn more about the Oncology Estimand ESIG, please check out our webpage www.oncoestimand.org or our [latest newsletter](#). It features

- the most recent achievements (e.g. [published and submitted papers](#)),
- upcoming [WG appearances at conferences](#) including links to slidedecks,
- and some further estimand-related resources.

Please do not hesitate to provide feedback or reach out to [Evgeny Degtyarev](#) or [Kaspar Rufibach](#) if you would like to get involved in the ESIG.

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Other ESIG news

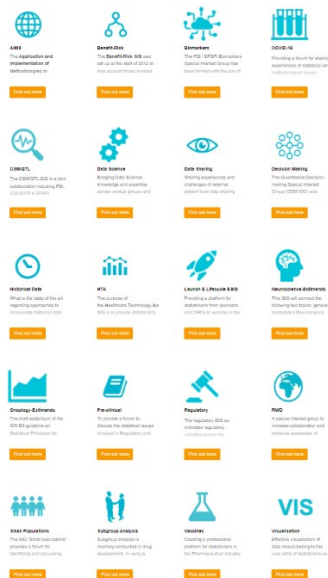


EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

Call to action!

Do you want to become our ESIG of the month? Then please contact [Emmanuel Pham](#) (EFPSI SIG liaison) or [Adam Crisp](#) (PSI Board SIG liaison lead) sooner than later and get the chance to be featured in our next newsletter.

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



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

The SIGs provide a forum for members to discuss topics of mutual interest, keep updated on developments in a particular area of industry, to organise events on their specialist field and/or to collaborate on developing the science of that field.

Our current SIGs cover a wide range of topics, for more details take a look at their pages on the [PSI SIGs website](#).

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Local Association of the month



Italian Biostatistics Group

The Italian Biostatistics Group (IBIG) is part of the Italian Society of Pharmaceutical Medicine (SIMeF, www.simef.it).

Currently, IBIG has about one hundred members!

IBIG's mission is to exchange information, share experiences and promote collaboration inside and outside of the group and it is open to people working in the industry, academia, and research institutes. The main activities of the group revolve around the organisation of meetings, courses and workshops concerning modern statistical methodologies, also including SAS and R topics. IBIG is also active partner of the CDISC community as it organises the Italian CDISC User Group Network Annual Meeting in collaboration with the country representatives.

The plan for 2022 foresees the second series of the monthly webinars "Statistical Pills" (started on 20th April) mainly targeted, but not restricted, to non-statisticians, with topics ranging from conventional themes such as essentials of trial analysis including interim analysis to more recent subjects like estimands and machine learning.

The annual IBIG forum will be held in Verona on 19th-21st October, with the usual format that consists of two pre-forum courses, one dedicated to the concept of QDM with a practical session on how to organise a Prior Elicitation meeting; the other one will be a deep dive into QC in programming. The two-day forum will be split into four sessions focusing on different areas of applied statistics.

In the last quarter of the year, IBIG will offer a course on multiple imputation with application in R / SAS and will participate in the organisation of the Italian CDISC User Group Network Annual Meeting.

A series of short webinars on tips & tricks in the use of the most common stats packages is under evaluation.

Finally, IBIG continues to collaborate with the University of Padua in the master in "Advanced Biostatistics for Clinical Research", by supporting students with tutorial and teaching activities and being part of the Board of the master.

Marco Costantini and Fabio Montanaro on behalf of the IBIG

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Other Country news

APF (Germany)

The German region (APF) is planning their yearly meeting (“Herbstworkshop”) on Friday, Nov 25th in Berlin (hosted by Cytel). Suggestions for topics and volunteers for presentations are highly welcomed and can be sent to [Frank Langer](#). One day before, on Nov 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.

BBS (Switzerland)

BBS/EFSPi Free Virtual Seminar on “Registry Studies and Health Technology Assessment (HTA)”

On Thursday, June 23rd from 15:00-17:00 CET, the Basel Biometric Society (BBS) and EFSPi are organising a virtual joint meeting on the use of disease and product registries in drug development and commercialisation, a topic which is receiving growing interest from pharmaceutical companies, regulators, and payers/HTA bodies.

This seminar presents new statistical and epidemiological approaches along with case studies that involve using registry data to improve accuracy in estimating and predicting outcomes in the real-world setting that aims to benefit patients and healthcare systems.

For further information about the speakers / topics being covered and to register, please click on the [flyer](#) on the EFSPi [website](#).

PSI (UK)



Registration for the 2022 PSI conference will close on June 10!

If you have not yet registered and would like more information on the conference, registration fees, etc. click this link: [PSI 2022 Conference](#).

PSI Pre-Conference Training Courses

This year the PSI Training Committee and the PSI Scientific Committee are delighted to offer two pre-conference courses. Both courses will run on **Sunday, 12th June 13:00–17:00** at Gothia Towers in Gothenburg.

- Estimand-aligned statistical analyses of clinical trial
- A practical introduction to simulating complex trial designs

Courses available for registration through the main conference registration portal, so please sign up when you register for the conference itself to avoid disappointment! [Find out more!](#)



Statistical Excellence in the Pharmaceutical Industry Award 2022

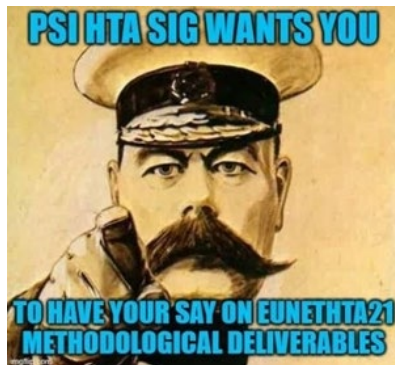
Nominations are being sought for this award, jointly run by PSI and the Royal Statistical Society (RSS). The award recognises an outstanding level of influence in the application of an existing statistical practice, or an innovation, that has strengthened the quality and efficiency of investigations in the pharmaceutical industry. Nominees can be based anywhere in the world and do not need to be a member of PSI or the RSS. The deadline for nomination is midnight **on Tuesday, 28th June 2022**. [Find out more!](#)

Ukraine/Russia War: Implications for Statistics

To date, it appears that the conduct of trials in Russia is largely unaffected by the war. In Ukraine however, trialists and sponsors do face a multitude of serious issues, e.g. destroyed source data, missing data, patients switching centres or even countries, or investigators unable to answer queries or provide signatures. The EMA has just published its “[Points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials](#)”. Find out more including the key topics on the [PSI website](#).

EUnetHTA 21 Public Consultation on Methodological Deliverables

The [EUnetHTA21](#) (European Network for Health Technology Assessment) will have a series of public consultations on draft guidelines. The focus will be the methods/processes used during the “interim period” as well as the future EU HTA system that will come gradually into force 2025.



Our PSI Healthcare Technology Assessment SIG will submit comments in relation (primarily) to the Methodological Deliverables, as well as selected Process Deliverables that have high statistical content/impact. We welcome any comments from PSI members who are interested to participate.

You can find further details about the EU Common Assessment and process & timelines relating to the EUnetHTA21 public consultation on our [HTA SIG webpage](#). If you have any questions please get in touch with [Emma Crawford](#).

MEETINGS, WEBINARS AND COURSES:

- 21st June 2022:** [PSI Pre-Clinical SIG Webinar: Assay Qualification by Linear Mixed Model - Confidence, Prediction & Tolerance Intervals](#)
- 29th June 2022:** [PSI Training Course: An Interactive Introduction to Agile Ways of Working](#)
- 30th June 2022:** [PSI EIWG Webinar: Impact of estimands](#)
- 4th July 2022:** [PSI Training Course: Hybrid Frequentist / Bayesian Power and Bayesian Power in Planning Clinical Trials \(TRNG278\)](#)

ON-DEMAND WEBINARS AND PODCASTS:

PSI VisSIG Wonderful Wednesday 26: Ordinal Scale for Improvement



The challenge of this month was to display COVID patient status over time as measured by the Ordinal Scale for Improvement. At the same time patient death or full recovery as well as patients leaving the hospital should be taken into account. All visualisations are available on the Wonderful Wednesday blog.

PSI Journal Club – Treatment Switching in Clinical Trials



This journal club features two papers on the topic of “Treatment Switching in Clinical Trials”. Watch now to hear Franz Koenig (Medical University of Vienna) and Juliane Manitz (EMD Serono) present their recent work.

The Effective Statistician Podcast in Association with PSI



[A Preview to the PSI Conference](#)

This is a special episode while Benjamin and I talk about the upcoming PSI conference and what you can expect from it. This will be a face-to-face conference in Gothenburg, Sweden!

[Patient-reported outcomes and the FDA Patient-Focused Drug Development Guidance](#)

We discuss the process with the FDA publishing a timeline of planned public workshops, draft guidance documents and final guidance documents for 4 documents, originally planned to finish in end 2021 and its objective to explore the factors that need to be considered when developing COA-based endpoints.

[Apps on prescription paid by the government](#)

Nowadays, there are a couple of available apps being used in several countries that collect user information, such as heart rate combined with algorithms that calculate certain health risks that the user may be vulnerable to. Dr. Stefan Walzer and I discussed the goal of the Digital Health Application.

Listen to these episodes and share them with your friends and colleagues who might learn from it. Ciao and be an effective statistician! Alexander Schacht

NON-PSI EVENTS:



43rd annual conference of the International Society of Clinical Biostatistics

Date: 21–25 August 2022

Location: Newcastle upon Tyne, UK



RSS 2022 International Conference

Date: 12–15 September 2022

Location: Aberdeen, UK

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Job opportunities

Nowadays, job opportunities for statisticians and 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.

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And finally...

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.



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](#).

And 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.

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