

# EFSPi Newsletter

OCTOBER 2022

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## WELCOME



### *A warm welcome to the October newsletter of EFSPi!*

Do you enjoy the autumn as much as I do? Unfortunately, the problems of the world have not disappeared but I am trying to stay positive, healthy, and focus on my circle of influence. My personal highlight is the nature's play of colours right now. While biking and hiking, I cannot stop looking at it before it puts on its winter dress soon.

I also see a lot of fantastic work going on at EFSPi. Please join me in exploring the news from our member associations and especially learn more about the French Statistical Society which is our EFSPi local association of the month!

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

Stay well, stay safe wherever you are!

Justine Rochon

EFSPi President and Editor of EFSPi Newsletters



## EFSPi COUNCIL NEWS

EFSPi stands for the European Federation of Statisticians in the Pharmaceutical Industry. The federation was launched in 1992 and is registered in Denmark since 2018. EFSPi is a non-profit organization, serving as an umbrella to constituted groups of statisticians. There is no individual membership, but we currently represent 10 national associations including more than 2000 statisticians in Europe.

Do you remember which national associations are EFSPi members?  
Can you match the right pairs?

### Let's play a memory game!

IBIG	SFdS	PSDM	FMS	DSBS
PSI	BBS	SBS/BVS	SSL	APF
				
				

If you want to learn more about our Member Groups, the EFSPi Council, our current priorities and work, please visit our website at [www.efspi.org](http://www.efspi.org) and follow us on [EFSPi LinkedIn](#).

## 5th EFSPI Council Meeting 2022

The EFSPI Council used to meet four times a year. The first three EFSPI Council meetings in 2022 took place fully virtual in January, April and July. In September 2022, we managed to meet in person. This was our first in-person meeting since 2019!

There is still much to do and we also have a lot to celebrate together! Therefore, the Council will exceptionally meet for a 5th time in December. Stay tuned to hear more about how we are going to finish this unprecedented year.

## EFSPI Regulatory Statistics Workshop

The 7th EFSPI Regulatory Statistics Workshop took place on 14–15 September 2022 as a hybrid meeting, with a focus on in-person attendance in Basel/Switzerland. For presentations, click [here](#).

This workshop was a truly memorable experience! Again, we want to thank the Scientific Committee and the local organizers, all presenters and panellists for their inspiring talks and input, and the fantastic audience for their lively interactions. Thank you also for your valuable feedback that will be used to improve our future events.

We already look forward to welcoming you back at the [Biozentrum Basel](#) next year!

**Save the date!**

The 8<sup>th</sup> EFSPI Regulatory Statistics Workshop will take place on 13–14 September 2023.



### Raw data submission pilot

The EMA has now published the pilot participation letter and the Q&A document, see [here](#).

Please note that the topic of data sharing is discussed under the heading of data privacy with a link to two documents, *EMA's data protection notice* and the *Records of data processing activity*.



### Patient experience data

We are pleased to share with you the [executive summary](#) of the 'Workshop on Patient Experience Data in EU medicines development and regulatory decision-making' held at EMA on 21<sup>st</sup> of September 2022 which is now published on the [EMA website](#).

It summarises the outcome of the discussions and the actions agreed to progress on Patient Experience Data in the EU. This multistakeholder workshop brought together patients, healthcare professionals, academia, regulators, and industry to discuss ways to improve the collection and use of patient experience data to achieve patient-centred medicine development and regulation.

EFSPI was invited to this workshop as one of the key stakeholders.



## ESIG News

### Joint PSI & EFSPi HTA ESIG Webinar: Statistics in EU HTA - PICO, Estimands & More

Starting in 2025, a system for HTA, not entirely unlike that of EMA for regulatory assessments, will apply to new medicinal products submitted for EMA regulatory review. The system will require manufacturers to submit an HTA evidence dossier broad enough to support each member state's evaluation of relative effectiveness within the context of their specific healthcare system. Is this a ripple that will matter mostly for statisticians specializing in HTA — or is it a splash that should be on all pharmaceutical statisticians' radar?

Join us on **14 November 2022** to gain a deeper awareness and understanding of how the new EU HTA regulation may affect not only HTA but regulatory processes.

Registration is now open and free for all to attend. Sign up [here](#)!

### Regulatory ESIG

The regulatory ESIG will have an informal meeting with the statisticians of the UK's MHRA end of November. If you have suggestions for topics to be discussed, please contact [Juergen Hummel](#) or [Christoph Gerlinger](#).

## LOCAL ASSOCIATION OF THE MONTH

### French Statistical Society



Bonjour! The Société Française de Statistique (SFdS) is a society founded in 1997, specialized in statistics, whose mission is to promote the use of

statistics and its understanding and to foster its methodological developments. To this end, it facilitates exchanges between statisticians from administrations, companies or educational or research institutions through a set of actions that are presented on this site. The SFdS was recognized as a public utility by decree of 3 December 1998.

The aim is to bring together all researchers, engineers, teachers, and users of statistics, whatever the nature of their functions and the place where they exercise them: it is thus a privileged place for meetings, exchanges and reflections. The current president is Anne Philippe.

There are 14 specialized groups within the SFdS. Among them, one is dedicated to "Biopharmacy and Health", in which statisticians from academics and industry collaborate together.

The SFdS organizes a number of events: every year there are so-called Annual Days over a week with changing location from year to year. There is now half a day dedicated to exchange with other European societies during these Annual Days. There is also a number of trainings organized by the SFdS.

The group "Biopharmacy and Health" organizes every year a yearly event on 2 days, generally in Paris. For about 3 years, this event has been organized jointly with the "GDR Santé" and the SFB (Société Française de Biométrie). On top of this, every four years, there is an International Congress organized by the group "Biopharmacy and Health". The last one took place in September 2022.

For more information, please consult <https://www.sfds.asso.fr/> or see [SFdS LinkedIn](#).

*Emmanuel Pham*  
French representative in the EFSPi Council



## IBIG (Italy)

For more than two years, virtual events were the only possibility to meet. Simply the fact that, this year, the IBIG Forum could be organized in a physical venue was perceived as a great achievement. From 19 to 21 October, the Italian biostatistics community gathered in the marvelous city of Verona at the Rita Levi Montalcini auditorium, kindly hosted by Evotec.

The atmosphere was just magic with not only perfect logistics but also amazing scientific content thanks to a great and well-mixed panel of speakers. Circumstances like this, plastically demonstrate the excellence of the group. Not only in terms of technical skills and methodological capabilities. It goes far beyond that: there is the human component which transforms a group of people in something more profound, where individuals bring ideas and share experiences just for the pleasure of being of help to other people. IBIG has no hierarchy, no leaders, no jealousy; it may seem utopic, perhaps it is, and this is why it is working so smoothly.

Almost 80 participants coming from different areas of expertise and business, embracing a wide range of ages, from young PhD students to senior company managers, discussed various topics from those that are hot topics nowadays, like Machine Learning and Estimands, through more established but always at the heart of the scientific debate, such as benefits, drawbacks, limits and potentialities of interim analyses and Risk Based Monitoring. Not to forget, a deep dive into programming validation with SAS and R and QDM principles and applications.

Merits along with an immense gratitude go to all who made this event happen!

The IBIG family is growing fast, maintaining its open and friendly nature on which it was founded. To learn more about us, please consult <http://www.biostatistici.it/>

*Marco Costantini for IBIG*



## FMS (Sweden)/DSBS (Denmark)



**Joint DSBS/FMS Meeting  
November 22  
Radisson Blu, Malmö**

Every second year the Swedish and Danish societies for biopharmaceutical/medical statistics, FMS and DSBS, arrange a joint meeting. This year's meeting will take place in Malmö, Sweden on November 22.

The theme of the meeting will be

**Data-driven research and decision-making in  
medicine and drug-development**

and there are four invited speakers:

Markus Lange, Novartis, will talk about their work on "Improving the assessment of the probability of success in drug development"

Marianne Månsson, Department of Urology, Sahlgrenska University Hospital, will present "Predicting bone metastasis in men with prostate cancer – from register data to nomogram"

Daniel Gedon, Department of Information Technology, Division of Systems and Control, Uppsala University, will talk about "Deep Learning-based ECG Reading in the Emergency Department – Diagnosis of Myocardial Infarctions"

Corine Baayen, Lundbeck, will talk about "Evaluating the probability of success of a trial or program based on multiple endpoints"

Registration deadline is **10 November 2022**.

Sign up [here](#) for this opportunity to join your colleagues to discuss and learn more about how to optimize the way through phase 2 and 3, and other applications of statistical methods in decision making!

*Anna Torrång for FMS/DSBS*

## PSI (UK)

The 2023 PSI Conference will be held face-to-face in Hammersmith, London on the 11–14 June 2023.

We are now taking submissions for any of your contributed oral or poster abstracts but with particular interest in the following:

- Estimands: methods, theory & case studies
- Analysis of 'big' data e.g. RWD etc.
- Bayesian
- Data visualization and animation
- Use of external data
- Health Technology Assessment
- Decentralized trials
- Innovative approaches
- Complex trial designs
- Use of R, Python etc.
- Analysis of Safety Data
- Master protocols and platform trials
- Non-technical topics e.g. leadership.

This year we are adding a new option to give a TED-style talk!

These talks should be only 5-10 minutes in length and can focus briefly on a big idea, a small idea, an issue or a solution. Please indicate on your abstract form if interested.

The deadline for oral abstract submissions is **18 November 2022**,  
for poster abstracts 25 February 2023.

As a reminder you can submit individual abstracts or abstracts for a full session. You can see the full list of abstract topics and download the abstract templates on the [website](#). It is also worth noting that anyone selected for oral presentation will be eligible for 10% off the three-day conference price.

All abstracts should be submitted to [PSI2023@wearemci.com](mailto:PSI2023@wearemci.com)

Conference registration will open soon, we look forward to seeing you in London!

### The Effective Statistician Podcast

[Listen here!](#)



**PSI 2023**  
CONFERENCE

NOVOTEL LONDON WEST,  
HAMMERSMITH

11-14 JUNE 2023



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



## 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.



Do you have 20 years of experience  
or 1 year of experience repeated 20 times?

- L. David Marquet

## 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 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.

Please share your thoughts with [Justine Rochon](#) and [Randi Grøn](#).

Call to action!



We are preparing for a special Nov/Dec  
'Xmas' edition of the EFSPI newsletter.

Let us know if you have anything you'd like to contribute!

