

EFSPI Newsletter April 2022

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Welcome

A warm welcome to the April newsletter from EFSPI!



I hope everyone is staying healthy and safe.

April was a very positive and productive month for EFSPI, even though the ongoing COVID-19 pandemic and the Ukraine/Russia war continue to impact our work and daily lives in countless ways.

I get many questions about our position but also if the current situation can bring some opportunities for EFSPI. As previously communicated, we stand with the international community condemning the war and the violence in Ukraine and against its people. We stand up together for solidarity, humanity, and peace.

We are also providing guidance to the EFSPI community. For example, this month's newsletter has important information about the impact of the Ukraine/Russia war on methodological aspects of clinical trials. In addition, you can read more about a new publication written jointly by clinicians and statisticians in Europe on their experiences of implementing ICH E9(R1). Even though the ICH E9(R1) addendum on Estimands and Sensitivity Analyses in Clinical Trials was introduced just before the COVID-19 pandemic, a positive outcome from the pandemic has been an acceleration in the adoption of the estimand framework, including differentiating intercurrent events related or not related to the pandemic. Finally, as you will see from this newsletter, we are ensuring EFSPI's business continuity while continuously further developing our federation at all levels.

Enjoy the reading!

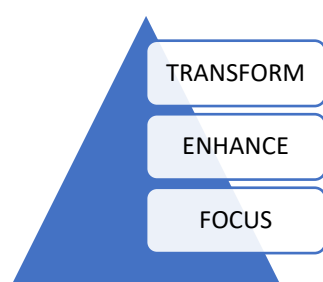
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EFSPI Council news

Update from the EFSPI Council Meeting

On April 26th, the EFSPI Council met virtually for the second time this year. Besides regular updates from the EFSPI president and the EFSPI office, review of budget and communication plans for 2022, we had some great topics for discussion and decision. First, we took a deep dive into the joint EFSPI/PSI webinars, acknowledged the impressive achievements across the ESIG Community but also carefully reviewed the corresponding webinar costs followed by a constructive discussion of a feasible funding proposal for future webinars. The next topic was about EFSPI's training strategy and our long-term ambition to create an EFSPI Training Academy. The first step towards this ambition is to clarify training needs and to share trainings across member organizations. Stay tuned to hear more about it as this proposal was just discussed with EFSPI member groups representatives on April 29th. Next, the Council clarified our position regarding incoming requests for EFSPI sponsorship, endorsement, and branding on promotional material. In addition, we reviewed the progress in the preparations for the two main EFSPI events planned for this year: The Statistics Leaders Meeting in July and the Regulatory Statistics Workshop in September, see more detailed information below.

Then we had a 45-minute workshop on EFSPI priorities for 2022 and beyond, in which we revisited our Council discussions from January and gained more clarity about how we as a team want to move forward to get things done.



The outcome of this very interactive workshop that was facilitated by an Agile Coach was an alignment on a three-step approach:

to FOCUS on ensuring business continuity, to ENHANCE our branding and visibility, and to further TRANSFORM into a federation that makes a difference today and in the future by engaging with key stakeholders, re-assessing the representation of member groups and clarifying our mission in the data science arena.

Finally, we discussed the implications of the Ukraine/Russia war (see summary below) and closed the meeting with a feedback round on what we should keep, stop or start doing to make our work in the Council more effective.

13th EFSPI Statistics Leaders Meeting

Approximately 40 EFSPI Statistics Leaders have been invited to attend the 13th meeting taking place on the 6th and 7th July 2022 in Basel, Switzerland which is being hosted jointly by Novartis and Roche. Three key themes will be discussed at this year's meeting: 1) Networking and collaborations with other groups, 2) Developing the next generation of statisticians, 3) Branding, behaviors and mindsets of statisticians.

A number of external keynote speakers and presenters from within and outside of the pharmaceutical industry are being approached to participate in this year's meeting and contribute to the discussions. The meeting will include several networking sessions for the majority of attendees being face to face but also for those who are attending virtually. The agenda will be posted in the coming weeks on the EFSPI website.

Chrissie Fletcher, Chair of the EFSPI Statistics Leaders

7th EFSPi Regulatory Statistics Workshop

7th EFSPi Regulatory Statistics Workshop
14th – 15th September 2022
Face-to-face meeting in Basel, Switzerland



Dates and times (CET):

Tuesday, 14th September 2022, 9-17 (+ 2h wine tasting)
Wednesday, 15th September 2022, 9-18

EFSPi is pleased to announce the 7th Regulatory Statistics Workshop that will take place on September 14-15th, 2022. We are planning the event in Basel with a focus on in-person attendance. However, sessions will also be broadcasted and recorded (all pending speaker approval).

The workshop will discuss opportunities and challenges of statistical topics in drug development between regulators, academics, and industry. The two days will be filled with various formats such as presentations, roundtable discussions, the well-established short topic session, lots of coffee breaks, and the legendary wine tasting.

Draft plans for the sessions are:

1. Introductory Keynotes on "What happened in the last two years in regulatory and HTA landscape"?
2. Subgroups generated by post-baseline variables: Can we expect causal conclusions?
3. Regulatory and HTA landscape for complex innovative designs in Europe: How can we move towards harmonization?
4. Generalizability and external validity: How to generate evidence about a treatment effect?
5. Role of statistics/quantitative science in regulatory decision-making
6. Short topic session

Note that these are draft titles and remain subject to updates.

We will also have a poster session where EFSPi/PSI ESIGs report on their work of the last two years.

We invite everyone to block their calendars! The announcement on the EFSPi website is [here](#).

Kaspar Rufibach, on behalf of the Local Organizing and Scientific Committee

Ukraine/Russia War: Implications for Statistics

The Regulatory ESIG and the EFSPi Council discussed the implications for clinical trials of the Russian attack on Ukraine. Most if not all international sponsors have stopped recruitment in both countries. Initially many statisticians felt that the situation is like a 'COVID 2.0'. However, on closer inspection only some of the methodological issues are similar to COVID while others are new.

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, drastically increased rate of patients lost to follow up, patients switching centers or even countries, or investigators unable to answer queries or provide signatures.



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

13 April 2022
EMA/214249/2022
Biostatistics Working Party

[Points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials](#)

The EMA has just published its “Points to consider on the impact of the war in Ukraine on methodological aspects of ongoing clinical trials” (for more information click [here](#)) with the following key points for statistics:

- Use the estimands framework to deal with events related to the regional crisis, i.e. revision of pre-specified estimand and/or addition of estimands may be warranted
- Intercurrent events related to the regional crisis to be addressed on the estimand level, i.e. hypothetical strategy to be considered
- Missing data due to the regional crisis to be dealt with on an estimation level, i.e. use of statistical methods aligned with the estimand of interest/MCAR assumption to be considered
- Sensitivity analyses may be required to assess the robustness of results to missing data assumptions.

To our knowledge no other health authority has published a guidance so far.

In the experience of the discussants in the ESIG and the EFSPi Council only a few trials of their respective companies were relevantly affected with some trials in Ukraine severely disturbed while others were virtually unaffected by the war. Hence, a trial-by-trial approach seems reasonable. All agreed that at the present state a solid documentation of the reasons for protocol deviations is key, as it is for COVID-19 related issues.

Special thanks go to Andrea Schulze (Bayer) and her “Statistics Working Group regarding Ukraine/Russia War”.

Christoph Gerlinger, on behalf of the Regulatory ESIG and EFSPi Council

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ESIG of the month

The Biomarkers Special Interest Group is our ESIG of the month!



Why a Biomarkers Special Interest Group?

It is probably no news to you that biomarkers are playing a bigger and bigger role in drug development. After a few years of hibernation, we have decided it is time to bring the Biomarkers SIG back to life!

Biomarkers Special Interest Group – rise from the ashes!

Our goals are

- to explore the hot topics of the moment when it comes to analyzing biomarkers data (OMICs, digital, imaging),
- to increase the interaction with other disciplines, be they medicine, biology, or academic research
- to connect with other Special Interest Groups.

In terms of topics to explore, here are a few that have come to our mind: incorporate prior biological knowledge and real-world evidence, machine learning & deep learning, digital biomarkers and imaging biomarkers, decision making based on biomarkers, estimands framework for biomarkers.

Who are we?

We are a diverse group of 20 enthusiastic people interested in biomarkers. We come from academia as well as the private sector (pharma, biotech).

Guillaume Desachy and Nicole Kraemer co-chair the group.

The kick-off meeting was held on April 20th, 2022. During this very productive meeting, we jointly brainstormed topics of interest for the months to come. We also discussed short-term and mid-term goals including a poster presentation at the PSI 2022 and a webinar for Q4 2022.

There will be monthly meetings! The next one is scheduled for May 18th, 9–10 CET.

Would you like to contribute?

The Biomarkers SIG wants to connect subject matter experts from various areas of application: pre-clinical or clinical development, untargeted or targeted biomarker data, and more. The more diverse the group, the more ideas will flow, so all are welcome! 😊

Please contact [Guillaume](#) and [Nicole](#) if you want to join the group.

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Other ESIG news

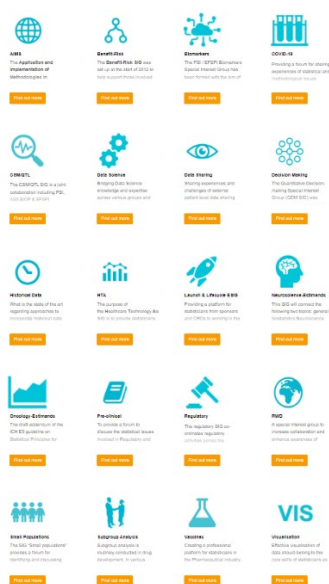
Estimand Implementation Working Group (EIWG)

The members of the EIWG are pleased to announce a new publication written jointly by clinicians and statisticians in Europe on their experiences of implementing ICH E9(R1) since the final guidance was released 2 years ago: *Marking 2-Years of New Thinking in Clinical Trials: The Estimand Journey*. The work was published online on April 24th in the DIA Therapeutic Innovation & Regulatory Science (TIRS) journal. To access the full publication, click [here](#).

What to expect from this publication?

The ICH E9(R1) addendum on Estimands and Sensitivity Analyses in Clinical Trials has introduced a new estimand framework for the design, conduct, analysis, and interpretation of clinical trials. The key lessons learned are discussed including what else needs to be done to continue the journey in embedding the estimand framework in clinical trials. Emerging best practices and recommendations are provided. Continued sharing of case studies will help to further advance the understanding and increase awareness across all clinical researchers of the estimand framework.

General



Our European Special Interest Groups (SIGs), sponsored by PSI and EFSPi, 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 organize 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](#).

For the names and contact details of our SIG leads, please refer to our [SIG Lead Contact Page](#).

For general enquiries please contact [Adam Crisp](#) (PSI Board SIG liaison lead) and [Emmanuel Pham](#) (EFSPi SIG liaison).

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Local Association of the month

DSBS



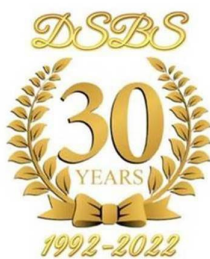
Danish Society for Biopharmaceutical Statistics

The Danish Society for Biopharmaceutical Statistics (dsbs.dk), was formed in March 1992 as an independent non-profit association. The aims of DSBS are to exchange of information between professional statisticians working for the pharmaceutical industry in Denmark and abroad, to promote professional standards, and to constitute an expert body in biopharmaceutical statistical matters. The DSBS currently has 231 members and the association typically arranges courses, late afternoon events for smaller groups of members to meet and discuss, and half or full day workshops with a selection of topics relevant to statisticians working with biopharmaceutical statistics.

From the outside perspective, this last year so far (!) has looked very quiet, but we have just been unlucky. The General Assembly in April 2021 was a reasonably quiet event, as we had to hold it virtually. Nonetheless, we hosted a webinar on COVID vaccines and on the regulatory background for the fast approvals. To somehow get started "after COVID", we later tried to arrange to meet on 13th September 2021, to at least listen to the EFSPi regulatory workshop and discuss it over drinks afterwards together. Unfortunately, it was not possible to meet as the company policies at the time meant that we could not meet at site at a company. Then, we agreed that in the middle of January 2022 Leo Pharma would host a meeting about taking leadership as a statistician. And, if anyone can remember that far back, it turned out to be bad timing again and we had to cancel the event, since having a lot of informal discussion on these topics across the group was a big part of the plan. However, as we found several interesting topics and speakers, it is an opportunity that we may re-use, as the topic is still relevant from our perspective. We had a number of courses in mind for 2021-2022, but it has turned out that the autumn of 2021 and January/February 2022 were not good times to meet 30 people in a small room across companies 😊.

For the next year, if we get the chance to do so, the plan is to set up a course in adaptive designs, maybe already in September 2022. Next, we would like to repeat the popular course in survival analysis that we have hosted on several previous occasions maybe in January 2023, and we are also considering a course in causal inference.

Most important, we stay optimistic!



And this 'big thing' just happened!

On 29th April 2022 we met more than half of the members in person as we had a full day Annual Meeting, with talks on estimands, decision theory, Cox proportional hazard, and more. The day ended with a party with live music and dancing to celebrate the 30 years jubilee of the DSBS!

Mette Krog Josiassen, on behalf of the DSBS Board

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Other Country news

PSI (UK)

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 on 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:



Over 320 people have already registered to attend the conference this year showing there is a clear appetite to meet face-to-face! Registration is still open! If you have not yet registered and would like more information on the conference, registration fees, etc. click this link: [PSI 2022 Conference](#).

We look forward to seeing you in Sweden.

David Lawrence PhD, PSI Conference Chair

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[PSI VIS SIG Webinar: Collaborative & Exploratory Data Analysis \(WEB277\)](#)

04

[PSI Training Course: Hybrid Frequentist / Bayesian Power and Bayesian Power in Planning Clinical Trials \(TRNG278\)](#)



[Listen here](#)

The best of causal inference

Miguel Hernán and I talk about how causal inference can help generate and analyze data to identify better strategies for the treatment and prevention of both infectious and noninfectious diseases.

To listen to this episode, just click [here](#).

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 September - 15 September 2022

Location: Aberdeen, UK

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Job opportunities

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

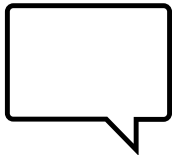
For information on how to submit recruitment adverts, please visit the [Job postings](#) on our EFSPi website. If you are currently seeking to hire a statistician and wish to post a job advert, EFSPi are offering one free advert for every 3 adverts posted on the website.

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And finally...

If you want to learn more about EFSPi, our Member Groups, the EFSPi Council and Operations Board, please visit our [EFSPi website](#).

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.



I value your feedback, so let me know what you think! What should I 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 visibility. Send your feedback to [me](#) and [Randi Grøn](#).

And finally, please help us to spread the word and promote our official [EFSPi LinkedIn page](#) and its contents. Encourage your network to follow EFSPi and engage with us by reacting to our posts, commenting or sharing.

You can also join our (closed) EFSPi group by requesting access to the [EFSPi LinkedIn Group](#) in order to exchange even more within our EFSPi community.



Stay well, stay safe wherever you are!

Justine Rochon, EFSPi President and Editor of EFSPi Newsletters

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