



Q1 2024 EFSPI newsletter

Dear EFSPI Community,

Welcome to the first quarter edition of our newsletter. As we step into a new year, we are excited to share with you the latest updates and achievements that have been shaping our organization. This quarter has been a period of growth and learning, and we are eager to take you on this journey with us.

We believe that transparency and communication are key to our shared success, and we hope this newsletter will serve as a valuable resource for you.

Thank you for your continued support and engagement. We look forward to an exciting and productive year ahead.

Best Regards,

Your EFSPI President

Egbert Biesheuvel



EFSPI President 2024–2025

EFSPI/EFPIA Estimand Implementation Working Group 2023 achievements 2

PSI/EFSPI Regulatory SIG Meeting with MHRA Statisticians on 8 November 2023..... 2

9th EFSPI Regulatory Statistics Workshop (11-13 September at Biozentrum, Basel) 3

Series of educational videos by the Estimands in Oncology SIG 3

PSI 2024 Conference..... 4

Draft FDA Guideline on Use of Data Monitoring Committees in Clinical Trials 4

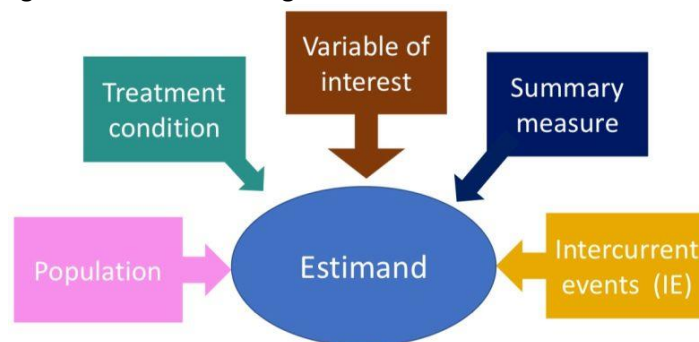
Sponsorship of national group and SIG group events 4

EFSPI members updates: 5

EFSPI/EFPIA Estimand Implementation Working Group 2023 achievements

The Estimand Implementation Working Group continues to bring together statisticians and clinicians to support the estimand implementation journey. Key achievements in 2023 were:

- One webinar organized on "Proposing Estimands from Different Perspectives" with over 800 people registered to attend
- One paper published on "Why Estimands are Needed to Define Treatment Effects in Clinical Trials"
- Four papers accepted/prepared on estimands in non-inferiority trials, bioequivalence and clinical pharmacology trials, reporting estimands and treatment policy estimation
- Multiple poster and conference presentations, including four presentations at the PSI Conference 2023 from the non-inferiority, early phase & clinical pharmacology, HTA & RWE, and reporting sub-teams
- Formed a new sub-team on "Intercurrent Events" to tackle uncertainty around the meaning of different intercurrent event strategies
- Two session proposals for the PSI Conference 2024 were submitted on non-inferiority studies and estimand thinking
- Provided comments on multiple regulatory guidelines
- General activities and achievements were made available on the EIWG homepage
- As of December 2023 the group has 45 members representing 27 companies and is led by Chrissie Fletcher, Amel Besseghir and Nanco Hefting.



PSI/EFSPI Regulatory SIG Meeting with MHRA Statisticians on 8 November 2023



Four statisticians from the MHRA and 18 members of the Regulatory SIG attended the meeting. As usual, it was an open and interesting exchange of information and ideas. The main topics of the discussion were intercurrent events of treatment switching and its handling for long-term outcomes, subgroup analyses and considerations about acceptability of novel endpoints for regulatory decision making. Detailed minutes from the meeting can be found on the PSI website [here](#).

9th EFSPi Regulatory Statistics Workshop (11-13 September at Biozentrum, Basel)



On 15 January, the Scientific Committee for the 9th EFSPi Regulatory Statistics Workshop was successfully kicked-off. The Scientific Committee members are actively engaging in ensuring an interesting, relevant and diverse scientific program and already at the kick-off meeting numerous proposals came up.

Like previous years, it is possible to submit a short topic for discussion with a panel of regulators. You can submit your proposal to the Chair, Helle Lynggaard, by sending it in an e-mail to hlyn@novonordisk.com (deadline 15 August 2024).

This year, we have extended the workshop by a half day (Friday morning) dedicated to in-depth discussions of HTA topics.

Information on the workshop is posted on the workshop website and it is updated regularly, so make sure to check it out. On the website you also find slide decks and recordings from past issues.

You should also already now block your calendar for next year's workshop, where we will mark the 10th anniversary of the workshop. It will take place at the same venue on 10-12 September 2025.

Link to workshop website: <http://www.efspiworkshop.org>

Series of educational videos by the Estimands in Oncology SIG

In 2024 Estimands in Oncology working group is releasing a series of short videos. In the videos the members of the WG do not only summarize key messages of their manuscripts, but also provide some personal reflections and learnings on the group's journey.

Evgeny Degtyarev and Kaspar Rufibach, the co-founders and co-leads of the WG, kicked it off with a conversation about the group's beginnings and their learnings. Interested to learn about their motivation to start the WG and how they did it? Wanna know more about how the WG was organized and some challenges?

Keep an eye on EFSPi, PSI and ASA Biopharmaceutical Section as they post the videos.



PSI 2024 Conference

The PSI 2024 Conference will be held from Sunday 16th to Wednesday 19th June 2024 as a face to face conference at Beurs van Berlage in Amsterdam, Netherlands.



The Conference program extends over 3 days and includes a variety of plenary and parallel sessions, as well as breakout discussion sessions, workshops, and a poster session. On the Sunday prior to the conference there are pre-conference course(s).

Registration includes multiple social events, including a welcome reception on Sunday evening, a networking event on Monday and, last but not least, the conference gala dinner on the Tuesday night. In addition, there are plenty of opportunities to interact with other delegates and sponsors at breaks.

Further details can be found here: <https://www.psiweb.org/conferences/about-the-conference/conference-registration>

Draft FDA Guideline on Use of Data Monitoring Committees in Clinical Trials

The FDA published for public consultation the guidance on Use of Data Monitoring Committees in Clinical Trials, available [here](#). The PSI/EFSPi Regulatory SIG collated comments to provide a consolidated response to FDA.

Sponsorship of national group and SIG group events

EFSPi is always at the forefront in sponsoring events and initiatives involving national statistical groups and SIG working groups affiliated with EFSPi. In particular, in this Q1 visibility was given to a workshop of the Pre-Clinical SIG and to some IBIG initiatives.

EFSPI members updates:

EFSPI is pleased to welcome two new members to the EFSPI council, who will represent the Basel Biometric Society. Kaspar Rufibach and Lilla Di Scala will assume the positions of Hans Ulrich Burger and Marisa Bacchi on the EFSPI council.



EFSPI wishes to express, once again, immense gratitude to Uli and Marisa for their significant contributions to EFSPI and BBS in recent years.

Additionally, EFSPI would like to thank again François Aubin and wish him all the best in his new phase of life after his retirement. François started as a member of the Scientific Committee in 1998 and has remained a member since then. Moreover, François has served as a council member for France for over 10 years and was EFSPI's President during the period of 2010-2012.

