

EFSPi regulatory statistics workshop 10th anniversary

EFSPi regulatory workshop, 10. Sept 2025

Uli Burger, Emmanuel Zuber and Egbert Biesheuvel

- A review: From friendly exchanges to a cornerstone workshop
by Emmanuel Zuber, Egbert Biesheuvel and Uli Burger
- A fireside chat about what has been in it for regulators
Kit Roes, Anja Schiel and Khadija Rantell
- Statistics Regulatory Workshop: Future Outlook
Julie Jones, Andreas Brandt, Elina Askinas, Jenny Devenport

10th Anniversary - Roots of the workshop

- DIA Statistics workshop starting in the early 90s
- Organized by DIA with an organizing committee consisting of statisticians primarily from industry and regulatory agencies
- Dedicated to the discussion between industry and regulators
- Was generally perceived as very valuable but interest declined over time
- Two joint meetings with regulatory agencies, one together with EMA and one together with BfArM
- But:
 - Workshop was also pretty expensive
 - Limited attendance: Usually by around 100 people plus minus, less in the last years
 - Last meeting in 2014

10th Anniversary - Roots of the workshop

- EFSPi started 2016 with a separate concept
- More affordable with a clear focus on content and discussion to increase participation
 - One location, no parallel sessions
 - Presentations always by invitation
 - Trying to have pragmatic and cost efficient solutions
- Location of Basel selected more from a pragmatic point of view
 - Basel is centrally located in Europe
 - Available local support (tremendously important for the event)
 - Large local biostatistics community
 - For some time we were thinking about alternating with Amsterdam, but it never really worked out so far...

- Collaboration between industry and regulators important and especially important on statistical topics
 - Biostatistics is a central part of clinical trials and drug development and by that it is also a central part of regulations. That is why we need to talk with each other
- The workshop should provide a forum for informal, open discussion, highly interactive, congenial interactions
 - Understand and learn from each other, with the same goal of high quality drug development

- The focus is always on discussions less on presentations
 - Presentations should motivate and guide the discussions
 - But the discussion is where the interaction takes place
- Focus is on principles and not on statistical methodology
 - For statistical methodology there are many other events
 - But we also need one focused on strategic and regulatory development principles
- When discussing development principles and strategies focus is on the why
 - The why is essential to foster common understanding between regulators and in industry
- Content should be focused on 'hot' topics
 - Hot topics either for industry or regulators provides maximum value
 - Identification of hot topics essential task of the scientific committee



10th Anniversary - Changes over time - Location

- First meeting 2016 in the old Biozentrum in Basel
- 2017 we could not get to the Biozentrum anymore, therefore moved to the Oekolampad church
- During Covid we had two virtual only meetings (2020 and 2021)
- Since 2022 we are now in the new Biozentrum with hybrid meetings

10th Anniversary - Changes over time

Old Biozentrum



10th Anniversary - Changes over time – Oekolampard Church 2017



10th Anniversary - Changes over time

New Biozentrum



10th Anniversary - Changes over time

- Leadership
 - Started with Uli, then changed to Kaspar
 - Introduction of a conference chair role (first Uli unofficially, then Kaspar, then Helle, now Vivian) together with guiding principles on organizer's renewal
- Duration
 - First meetings 1.5 days
 - Then changed to 2 days
 - Since last year 2.5 days
- Scientific committee
 - In the beginning more ad hoc and informal
 - Support from regulatory always crucial but requiring quite a visionary energy in the beginning (Norbert Benda and Armin Koch especially!)
 - Later then changed to a more formal selection and diverse scientific committee
 - Scientific committee growing from 8 to 27 people!

10th Anniversary - Changes over time

- Focus
 - Original focus solely on topics for regulators and drug approval
 - Over time opened up to HTA topics as we see the need for discussing both together (but HTA landscape is different than the regulatory landscape)
- Geography
 - From the beginning we wanted to connect Europe more globally (e.g. first meeting had a virtual presentation of Tom Permut, FDA)
 - Later, we systematically opened up to other regions as well (Japan, China...) as our environment is really global
 - Attendance from North America and specifically from Asia increased over time with the possibility of virtual attendance since 2020
- Developed more formal partnership with the FDA Industry workshop starting in 2023

- Informal, open interaction on content
- Openly sharing views and opinions
- Drive to innovate
- Voluntary engagement
- Focus on low workshop fees
- Long breaks for networking
- Wine tasting
- ...



10th Anniversary - Thank you!

- There are lots of people to thank without whom this workshop would not have been possible
- There are lots of people who significantly contributed to the success
- There are all of you attending who made the workshop in the last 10 years so valuable!

10th Anniversary - Thank you!

- Local organizers

Uli Burger, Emmanuel Zuber, Egbert Biesheuvel, Christoph Gerlinger, Kaspar Rufibach, Helle Lynggaard, Vivian Lanius, Jenny Devenport, Julie Jones

- Regulators

Norbert Benda, Armin Koch, David Wright, Khadija Rantell, Frank Pétavy, Ferran Torres, Anja Schiel, Kit Roes, Rob Hemmings, Andreas Brandt, Benjamin Hofner, Flavia Lombardo, Cecilia Hedlund, Maria Grünewald, Lorenzo Hess, Aldana Rosso, Steven Teerenstra, Eftychia-Eirini Psarelli, Elina Asikanius, Aandreas Kirisits, Florian Klinglmueller, Francois Maignen, Lukas Aguirre Dávila, Heidi Mestl, Wolfgang Jacquet, Anouk Neven, Seamus Kent, Rafael Sauter

- Industry members

Randi Gron, Viktoriya Stalbovskaya, Corine Baayen, Fredrik Öhrn, Giulia Zigon, Anders Gorst-Rasmussen, Bergrún Tinna Magnúsdóttir, Pierre Mancini, Claudia Dallinger, Patrick Schloemer

- Academia

Tim Friede, Franz König, Thomas Jaki, Nigel Stallard, Ina-Christine Rondak, Aldana Rosso

- Support

Bibiana Blatna, Laurence Guillier, Dora Guenther Vegsoeova and Carmen Pasquale

10th Anniversary - Thank you!





10th Anniversary - A fireside chat about the value of the workshop for regulators

Anja Schiel, Khadija Rantell and Kit Roes

Statistics Regulatory Workshop: Future Outlook

Julie Jones, Andreas Brandt, Elina Askinas, Jenny Devenport

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