

Summary of 2023 EFSPi Statistics Leaders Meeting

The 2023 EFSPi Statistics Leaders meeting was co-hosted by GSK and AZ. Twenty-five leaders from Industry, representing Pharma, Biotech and CRO companies, joined the meeting in person at GSK House in Brentford and 9 leaders participated virtually.

Following a short introduction by Chrissie Fletcher (EFSPi Statistics Leaders Meeting Chair) and Justine Rochon (EFSPi President), the EFSPi Leaders met with Chris Corsico, SVP Development, GSK. Chris gave very motivating and inspiring perspectives of the critical role for statisticians in R&D, where their strategic insights, valuable contributions to drive quantitative decision making and use of innovative clinical trials and real-world studies to accelerate evidence generation is needed more than ever before. Chris' call to action was for the EFSPi Statistics Leaders community to be role models for their groups, to inspire the NextGeneration of statisticians and data scientists to be ambitious for patients and be a strong voice at the table in decision making, especially with the evolution of broader and more diverse sources of data. He asked for statisticians to be telling stories, what the data tells us but also what the data doesn't tell us.

Three statisticians, Jenny Wissmar (AZ), Arina Kazimianec (GSK) and Evanthia Koukouli (Novartis), were invited to attend the first day to share their careers to date (see Session 1 below) and also to lead an ice-breaker session. The ice-breaker started with a pre-recorded video to explore how the use of ChatGPT could influence the future of statistics, which was very entertaining, and then a series of games followed. The first game was the 'Career Reflection' game where leaders were asked 'What advice would you give yourself to do more of 15 years ago?'. The second game was the 'Distributions' game where leaders needed to match modified dinosaur names reflective of their profile shapes to statistical distributions, identify fake statistical distributions, match distributions with the name and date of their discovery, and match the distributions with the correct kurtosis terms. It was so much fun, please play the games in your organisations and test your knowledge!

Session 1 explored the impact of quantitative sciences on strategic decision making in our organizations and how to enhance it, including through the development of our early/mid-career statisticians. It comprised 4 parts: a review of the leader's survey results, an inspirational speech by Steve Ruberg, presentations from early/mid-careerists on their experience and needs, and breakout discussions to define actions for leaders and for EFSPi.

- Leaders Survey debrief:
 - we report some influence on strategic decision making primarily in clinical development, including portfolio management, to a good extent in access as well, and less in other areas such as manufacturing or pre-clinical/
 - this occurs through our direct engagement on projects, as well as in decision boards, bringing our analytical thinking as well as different tools, from traditional outputs to probabilities of success, decision criteria, more sophisticated data visualisation or quantitative scenario analyses
 - there is plenty of room for improvement and our strengths become at times our hurdles, including our -too ?- technical focus, our self-perception and perceptions of others, and our communication style including a certain conservatism

- Steve Ruberg's presentation:
 - Through a lively and well-illustrated talk, Steve invited us to engage in a deliberate plan to enhance our strategic impact, and proposed 6 key leadership principles to drive this change, delineating a strategic roadmap for success

- Those points included
 1. A very focused vision
 2. Developing skills
 3. Providing the right incentives
 4. Collaborative and prioritized resource management
 5. An aligned action plan
 6. Explanatory and motivating communication, marketing the value we bring

- Three early/mid-careerists shared their experience in strategic influence of decision making. Their very candid, very mature and eye-opening presentations were inspiring and thought provoking. They advocated the value of being exposed to a diversity of drug development and collaboration situations, e.g., through rotations, their needs for leaders with a clear vision and expectations, who are role modeling and sharing their stories, who are also good listeners, accessible mentors creating a safe learning environment, and who are including, trusting and challenging as managers.

- The breakout sessions investigated more deeply our current status, enablers and hurdles of our influence of strategic decision making, with a focus on key stakeholders (decision makers), first line people managers and developers, and trial and project statisticians. Teams identified the following possible actions, in addition to those proposed above by early/mid-careerists:
 - For leaders:

Be clear on vision and expectations, provide incentive and acknowledgement, share successful examples and experiences of impact, provide access to networks, expose team to stakeholders, provide context and system awareness (including “business jargon” and stakeholders needs), explain big picture and give feedback, be open to learn from younger generation, offer education cross-functionally (“stats without the Greek letters”)
 - For EFSPi:

Continue to include the younger voice in the leader’s network, provide cross-industry networking forum for early/mid-career statisticians, invite speakers and host sessions about influencing skills, leadership trainings and material repository, sharing cross-industry examples and survey results, propose mentoring system

At the end of Day 1, the leaders met for dinner hosted by AZ and continued their networking and sharing experiences.

The second day started with Session 2 which explored a decade of data sharing, what have we learnt and what does the future look like. Martin Posch (University of Vienna) discussed various types of data sharing, such as sharing data from multiple trials or multiple arms within a platform trial, sharing control group data only, or sharing data across treatment arms. He provided an overview of the potential uses of shared data, ranging from quality assessment of published analyses to addressing novel research questions and statistical methods development. An important consideration is the robustness of shared data analyses, which are typically retrospective analyses, and the related potential biases. Martin addressed the importance and meaning of pre-specification when analysing shared datasets. He also discussed the challenges in implementing data sharing from the perspectives of data owners and researchers accessing shared data and shared an upcoming EU-ITN doctoral program on clinical trial data sharing which aims to address the need for

comprehensive training in statistics, data standards, meta-science, and legal and social issues to effectively implement data sharing.

Mimmi Sundler (AstraZeneca) and Rebecca Sudlow (Roche) gave their reflections on a decade of data sharing, what has been learnt and what the future might look like for data sharing. EFPIA/PhRMA Principles on Data Sharing were established in 2013 and became effective in 2014 when the EMA published Policy 70. In more recent years Journals have improved their data sharing to enable published work to be better scrutinized. In Europe, the General Data Protection Regulation (GDPR) became effective in 2018. The pharmaceutical industry has greatly improved their data sharing via disclosure on clinicaltrials.gov, providing redacted Clinical Study Reports and publications of peer reviewed studies. Third part access to patient-level analysable datasets has also been enacted. The session also covered information on the different data sharing platforms, how the choice has evolved over time and the hope that one platform will become the default across the world in the future. The future also offers the possibility of large data sharing initiatives – this was in part inspired by necessity during the COVID pandemic, and this has led to an appreciation of the value these initiatives provide.

In the Breakout sessions there was a discussion on how much data sharing knowledge statisticians need to have. There was consensus that statisticians should have a general awareness of data sharing best practice and the value data sharing brings. It was suggested that the EFSPi Council should consider supporting a whitepaper on how to do data sharing to promote the importance of good data sharing practices across the pharmaceutical industry which could benefit small to mid-size Pharma. There was also agreement in the breakout sessions of the value data sharing can bring to drug development. There was an appreciation in the time and resource needed to give access to data and participants wondered if there needed to be more of an incentive to providers of data to acknowledge the effort needed to get the data ready to share. It was suggested that the Data Sharing SIG should share case studies of successful internal data sharing to help others convince their organizations of the value this brings. Finally, it was suggested that EFSPi collaborate with EFPIA (who also have a data sharing group).

Session 3 explored how Statistics functions are evolving including the scope of accountabilities, new roles emerging, and how statistical leaders are developing themselves as future modern leaders. In the survey results, leaders noted what they are prioritizing for their own personal development and shared their own rating of management style, with the majority of leaders reporting a 'coaching' style. Three quarters of the survey responders noted their Statistics function is going through or is planning to implement major organisational transformations and ~50% of survey responders noted they have created or are planning to create new role(s) in their organisation. In a word cloud of the future evolution of statistics and data science, three key themes emerged: data insights, artificial intelligence and clinical development.

From the breakout sessions, what makes a great leader is owning a vision and having a concrete action plan. A great leader has grounded authenticity and magnetism that provides purpose, meaning and direction and they will take ownership of change management and chart the course. In terms of what is changing and what will be needed in the future to manage statistics groups, there is growing and welcome diversity in the pool of statisticians joining the Pharmaceutical Industry and types of statistician roles. For example, statisticians may have one or more of the following areas of focus: leading projects, leading methodology, leading operational delivery and/or leading groups. Critical skills remain essential for all statisticians, but ways of working have changed significantly since the COVID-19 pandemic. The way in which statisticians learn, train, and be a voice at the table

is different and requires strength in communication, influencing and leadership skills. Accountabilities of statistics groups are also much broader with increasing levels of seniority within an organisation. This brings more influence and empowerment and also more expectations to impact and add value. Statisticians are expected to be able to deal with more complexity and be at the table in key governance boards as strategic drug developers. There is a call to action to strengthen the interpretation of results, enhance entrepreneurial skills and share success stories.

Key actions for the EFSPI leaders are to challenge themselves, be curious, be deliberate in communication strategies, share their experiences, not to get hung up on role titles (statisticians versus data science), support and guide their groups through change and consider writing a position paper summarising recommendations and best practices. Key actions for the EFSPI Council included opportunities to help support EFSPI grow statistical leadership capabilities and leading analytical teams, reviewing what is an 'appropriate qualification' for a statistician, remain open and welcome different areas of interest and explore other industry sectors to see what could be learned.

The meeting ended with the session chairs, Emmanuel, David and Chrissie, and the EFSPI President, Justine, thanking everyone who attended the meeting (in person and virtually) for their valuable contributions and to GSK and AZ for hosting the meeting.

The 2024 EFSPI Statistics Leaders meeting will be hosted by BMS in Boudry Switzerland. Further information will follow in due course.