



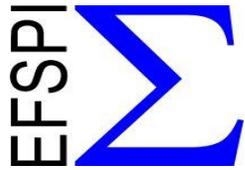
European Federation of Statisticians in the Pharmaceutical Industry
Representing Statistical Associations in Europe

Reflections and lessons learnt of EFSPI Statistics Leaders Meetings 2010-2018

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3-4th July 2019, 10th EFSPI Statistics Leaders Meeting

Agenda

- What did we set out to do in 2010?
- Brainstorm: What great things can we achieve in the next 10 years?
- Reflection: Key themes and topics covered in previous meetings
- What have we learnt from the last 9 years?
- Summary



Statistical Leaders Meeting Objectives

- Develop a forum for Statistical Leaders to
 - Network and share ideas
 - Shape and influence our environment
 - Education & Continuing Professional Development
 - Methodology Development & Identification of Best Practice
 - Regulatory and Industry policies
 - Effective working with differing resourcing models
 - Help to shape the strategy for EFSP

Statistical Leaders Meeting is different

Statistical Meeting

- Technical
- Experts
- Focus on past
- One way
- Presentations
- Reactive audience
- To listen



Statistical Leaders Meeting

- Strategic
- Managers
- Focus on future
- Interactive
- Workshops, Roundtables
- Active participants
- To act



What great things can we achieve in the next 10 years?

What are the 3 top priorities to achieve in the next 10 years of EFSPI Statistics Leaders meetings?

Key themes covered in the meetings

Year 1 (2010)

- Profession Development for statisticians
- Benefit-Risk Assessments
- Health Technology Assessments

Year 2 (2011)

- Model-based drug development
- Comparative drug effects, network meta-analyses
- Accreditation of Pharmaceutical Statisticians
- Totality of evidence

Input and feedback on EFSPI strategy and priorities

Key themes covered in the meetings (cont.)

Year 3 (2012)

- Adaptive statisticians beyond clinical trials
- Career paths for statisticians in Pharma
- Strategy workshop
- SIGs update

Year 4 (2013)

- Clinical data transparency
- SIGS – Medical devices, Benefit-risk

Input and feedback on EFSPI strategy and priorities

Key themes covered in the meetings (cont.)

Year 5 (2014)

- Clinical trial data sharing
- SIGs – Integrated Data Analysis, Pharmaco-epidemiology
- Recent developments & survey results

Year 6 (2015)

- Statisticians adding value to HTA
- Stats leadership on data sharing
- Regulatory interactions
- SIGs – rare diseases, benefit-risk
- Real world evidence
- Estimands

Input and feedback on EFSPI strategy and priorities

Key themes covered in the meetings (cont.)

Year 7 (2016)

- Regulatory interactions
- SIGs – small populations, modelling & simulation, AIMS
- Precision medicine

Year 8 (2017)

- Decision making
- Collaborating with academia
- Patented trial design
- Data science

Input and feedback on EFSPI strategy and priorities

Key themes covered in the meetings (cont.)

Year 9 (2018)

- SIGs – quantitative decision making
- Accelerating clinical trials – using historical data for controls
- Pragmatic trials and external controls
- EFSPI-led training

Year 10 (2019)

- Reflections of the last 9 years
- Improving critical leadership skills for statisticians
- Apply agile methods
- Making our statisticians bold and entrepreneurial
- Round table discussions

Input and feedback on EFSPI strategy and priorities

Did we achieve our goals?

Absolutely!

What have we learnt from the last 9 years



Key focus on the changing role of the statistician



Slow to change, missed opportunities?



Importance of professional development and leadership capabilities



Slow to learn new skills, reduced impact/scope?



Tremendous value of the SIGs with significant impact in key areas of drug development



Challenging to support and oversee the SIGs



Power and strength of the statistical leaders network and influencing EFSPi strategy



Could we do more together in between meetings?

Summary

Thank you for your support to EFSPi and the EFSPi Statistics Leaders Meetings

Fun

Workshops

Inspiring

Competitive

Challenging

Surveys

Open

Discussing

Networking

Engaging

Sharing

Interactive

Teamwork

Brainstorming