PSI/EFSPI Regulatory European Special Interest Group (ESIG)

Objectives

- Review of regulatory guidelines and policies to provide consolidated cross industry responses
- Identification of regulatory statistical issues that are of concern across industry for discussion with regulators
- Engagement with MHRA statisticians and EMA Methodology Working Party
- Promotion of best practice and driving debate on future guidelines

Membership

- 20 members from 8 countries and 20 companies,
- led by **Jürgen Hummel** (Novo Nordisk, UK) for PSI and **Christoph Gerlinger** (Bayer, Germany) for EFSPI

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Purpose

To co-ordinate regulatory activities across the European Pharmaceutical Statistical community and to engage with Regulatory statisticians

Notable activities

- Scan regulatory guidelines for statistical content and comment
- Annual meeting with MHRA statisticians
- From 2013 to 2021, annual meeting with EMA Biostatistics Working Party
- Help to organize the EFSPI workshop on Regulatory Statistics and the PSI training course: Regulatory Guidelines for Statisticians
- Connect with other ESIGs

History

- The Regulatory ESIG is probably the longest serving ESIG, dating back to at least 2006
- It was originally formed as a PSI Regulatory Committee and transitioned to a joint PSI/EFSPI Committee around 2013
- At the end of 2020 it renamed from a Committee to an ESIG

Find us online

EFSPI EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe