

# Regulatory ESIG



## Purpose:

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

## Objectives:

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

## Activities:

We have been meeting annually with MHRA statisticians for an informal exchange of statistical topics important for both regulators and industry for over 15 years. Our most recent meeting was on 23 November 2022, which was held virtually. The format worked very well, and the main topics of the discussion were planning for safety assessments, dose optimization in oncology and statistical methods for small populations. Detailed minutes from the meeting were published in SPIN) and via the Regulatory ESIG webpage.

Since 2013 we have also been meeting annually with the statisticians of the EMA Biostatistics Working Party for a similar exchange of statistical topics important for both regulators and industry. With the dissolution of EMA's Biostatistics Working Party discussions now take place at the annual EFSPi regulatory workshop in Basel.

## Activities cont.

We scan all new draft regulatory guidelines for statistical content and comment if needed. In 2023 we commented on the FDA draft guidance on Statistical Approaches to Establishing Bioequivalence.

We will also actively participate at the ACT EU Priority Action 8 workshop on guidance on clinical trial methodology that will take place on 23 November.

## History:

The Regulatory European Special Interest Group (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.

## Membership:

Leaders of the Regulatory ESIG are:

PSI Lead: Jürgen Hummel (PPD, UK)

EFSPi Lead: Christoph Gerlinger (Bayer, Germany)

We have 21 members from 7 countries and 20 companies:

Meet all our members on our website :

