

# Interactions with Regulators in EU

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EFSPI regulatory chair

# EFSPI/PSI Regulatory Affairs Committee

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- Co-ordinates review of regulatory guidance within EFSPI members
- Chair Christoph Gerlinger (EFSPI), co-chair Lesley France (PSI)
- Members
  - UK: Alan Phillips, Alun Bedding, Chrissie Fletcher, Daniel Evans, Frances Lynn, Jon Blatchford, Julie Anderson, Jürgen Hummel, Kerry Gordon, Lesley France
  - FR: Maylis Coste; SE: Per Larsson; DE: Christoph Gerlinger, Ruthild Sautermeister
  - Companies: Amgen, AZ, Bayer, Biogen, BI, GSK, Icon, Medicomp, Novo, Pfizer, Quintiles, Roche, Servier
  - [Additional members from continental Europe welcome](#)

# Key activities in the past year

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Meeting with MHRA statisticians 2014-06-16

Summary published in SPIN spring 2015

Meeting with BSWP 2014-09-05

First ever meeting of a CHMP WP with industry counterpart

Commented on subgroup guidance

Presentation at EMA workshop 2014-11-07

# Upcomming activities

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- Meeting with MHRA statisticians (Sep, 14<sup>th</sup>)
- Meeting with BSWP (Oct tbc)
- Comments on FDA guidance on Adaptive Design for Medical Device Clinical Studies
  - First round due by this Friday
- Expert groups to prepare for commenting
  - Estimands
  - Post-Authorisation Efficacy Studies (EMA)
  - Statistics in CMC (no volunteers yet)

# Your input please:

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What are your hot topics to discuss with regulatory statisticians?

How should we circulate the results of our interactions?

How to engage more colleagues from mainland Europe?