Interactions with Regulators in EU

Dr. Christoph Gerlinger
EFSPI regulatory chair
EFSP/PSI Regulatory Affairs Committee

- Co-ordinates review of regulatory guidance within EFSP members
- Chair Christoph Gerlinger (EFSP), 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

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
Upcoming activities

Meeting with MHRA statisticians (Sep, 14\textsuperscript{th})
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:

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?