

3rd Joint Conference of European Human Pharmacological Societies (AGAH, Club Phase I, BAPU, AHPPI)

European Competitiveness in Early Clinical Drug Development:
threats and opportunities

21 – 22 May 2015
Brussels, Belgium

CLUB PHASE 1



SUARE
BRUSSELS MEETING CENTRE

**3rd Joint Conference
of
European Human Pharmacological Societies
(AGAH, Club Phase I, BAPU, AHPPI)**

**European Competitiveness in Early Clinical Drug
Development: threats and opportunities**

Pre - conference 1-day workshops : 20 May 2015

2 parallel workshops : starting around 10 – 10:30 am

Workshop 1: Recent changes in EU Regulations & Guidelines: threats and opportunities

Workshop 2: Pharmacokinetic – pharmacodynamic modelling

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Sessions

- Open forum discussion: In the light of the new Clinical Trial Regulation: what does the future of phase I research look like in Europe?
- Advantages of early development of medicinal products in Europe
- European setting for early drug development in special populations
- Clever approaches to navigating research challenges
- Development of biosimilars: why is Europe the place to be?

Workshops

- Efficacy and safety prediction with tissue and animal models
- Inspections and audits: what can be learned?
- New statistical tools for modeling dosing regimens for FIM and proof of concept studies
- Outlook on the upcoming medical device and in vitro diagnostics regulations in the EU