



KENSINGTON CONFERENCE AND EVENTS CENTRE  
LONDON, UK  
17-19 MAY 2017

# PRE-CONFERENCE WORKSHOP PROGRAMME

17 May 2017

EXPLORATORY MEDICINES DEVELOPMENT:  
INNOVATION AND RISK MANAGEMENT



EUROPEAN FEDERATION FOR EXPLORATORY MEDICINES DEVELOPMENT

[www.eufemedconference.com](http://www.eufemedconference.com)

## Preconference 1-day workshop: 17 May 2017

### Practical aspects of assessing and mitigating risk in early phase clinical trials

- 10:00 Welcome (Jan de Hoon)  
Chairs: Jan de Hoon & David Jones (MHRA)
- 10:15 Toxicological risk assessment for early medicines development: case studies & discussion.  
*Stephanie Plassmann, Switzerland*
- 11:05 Other preclinical risk assessment strategy: Computational Systems Toxicology and in silico prediction of off-target activities. Case studies & discussion.  
*Friedemann Schmidt, Germany*
- 11:55 Dose selection based on Minimal Anticipated Biological Effect Level (MABEL) for biologicals and high risk small molecules: case studies & discussion.  
*Bruno Boutouyrie, France*
- 12:45 Lunch  
Chairs: Kerstin Breithaupt and Kirsty Wydenbach (MHRA)
- 13:45 Determination of the first dose for multispecific monoclonal antibodies: practical examples.  
*Marc Pallardy, France*
- 14:15 Is the concept of maximum tolerated dose useful for medicines development in humans?  
*Philippe Grosjean, France and Eric Legangneux, Switzerland*
- 15:00 Break
- 15:15 A regulatory update on the EU guideline on First-in-Human clinical trials.  
*Thomas Sudhop, Germany*
- 15:45 Statements from European Competent Authorities: Milton Bonelli (EMA), David Jones (MHRA, UK),  
*Greet Musch (FAMHP)*
- 16:15 Open forum discussion with all speakers and EU representatives
- 17:15 End of Workshop
- 17:15 – 19:00 Welcome reception and registration