PRE-CONFERENCE WORKSHOP PROGRAMME

17 May 2017

EXPLORATORY MEDICINES DEVELOPMENT: INNOVATION AND RISK MANAGEMENT
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)

       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

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

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