CONFERENCE PROGRAMME

EXPLORATORY MEDICINES DEVELOPMENT: INNOVATION AND RISK MANAGEMENT
PROGRAMME COMMITTEE

AGAH, Germany: Dr Kerstin Breithaupt, Dr Ingrid Klingmann, Professor Hildegard Sourgens
AHPPI, United Kingdom: Dr Michael Hammond, Dr Ulrike Lorch, Dr Jorg Taubel
BAPU, Belgium: Professor Jan de Hoon, Professor Luc Van Bortel
CLUB PHASE I, France: Dr Henri Caplain, Dr Yves Donazzolo

Local organising committee (AHPPI): Mr Tim Hardman, Dr Ulrike Lorch, Mr Steffan Stringer

CONFERENCE FACULTY

Dr Elizabeth Allen, Quintiles, UK
Professor Dr Christian Blank, Netherlands Cancer Institute, The Netherlands
Dr Milton Bonelli, European Medicines Agency (EMA)
Dr Bruno Boutouyrie, Novartis, Switzerland
Professor Alan Boyd, Faculty of Pharmaceutical Medicine, UK
Dr Kerstin Breithaupt-Groegler, kbr – clinical pharmacology services, Germany
Dr Henri Caplain, Club Phase I, France
Dr Philippe Danjou, Biotrial, France
Dr David Jones, Medicines & Healthcare products Regulatory Agency (MHRA), UK
Professor Dr Jan de Hoon, UZ Leuven, Belgium
Professor Saskia De Wildt, Radboud University Medical Centre, The Netherlands
Dr Yves Donazzolo, EUROFINS OPTIMED, France
Dr Katharina Erb-Zohar, Clinphase, Germany
Professor Ann Gils, University of Leuven (KULeuven), Belgium
Dr Christopher Goldring, University of Liverpool, UK
Professor Roberto Gomeni, PharmacoMetrica, France
Mr Philippe Grosjean, Sanofi, France
Professor Geoff Hale, Freelance Scientist, UK
Dr Mike Hammond, Clinical Quality Management Solutions Limited, UK
Mr Tim Hardman, Niche Science and Technology, UK
Professor Elaine Holmes, Imperial College, UK
Dr Ioannis Karydis, Southampton General Hospital, UK
Dr Ingrid Klingmann, Pharmaplex, Belgium
Dr Eric Legangneux, Novartis, Switzerland
Mr Peter Liedl, Boehringer Ingelheim, Germany
Dr Ulrike Lorch, Richmond Pharmacology, UK
Dr Stuart Mair, Quotient Clinical, UK
Professor Christoph Male, Medical University of Vienna, Austria
Dr Greet Musch, Federal Agency for Medicines and Health Products, Belgium
Dr Heike Oberwittler, Ipsen Innovation, France
Professor Marc Pallardy, Paris-Sud University, France
Ms Annick Peremans, Research Centre Aalst, Belgium
Dr Jean-Louis Pinquier, International Society of Pharmacometrics, France
Dr Stephanie Plassmann, PCS Consultants, Switzerland
Professor Dr Sylvie Rottey, Ghent University, Belgium
Dr Friedemann Schmidt, Sanofi, Germany
Dr Barbara Schug, SocraTec R&D, Germany
Professor Hildegard Sourgens, Sourgens Consulting, Germany
Professor Thomas Sudhop, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany
Dr Jorg Taubel, Richmond Pharmacology, UK
Professor Dr Luc Van Bortel, Ghent University, Belgium
Professor Johannes Van den Anker, Children’s National Health System, USA
Dr An Van Den Bergh, Johnson & Johnson, Belgium
Dr Kirsty Wydenbach, Medicines & Healthcare products Regulatory Agency (MHRA), UK

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Day 1 Thursday 18 May 2017

08:00 Registration

08:30 Welcome and Introduction to the 1st EUFEMED conference

08:45 Keynote: Incidences happen – which lessons can we learn? 
Jan de Hoon, Belgium

Session 1: Managing risks in early phase clinical trials 
Chairs: Hildegard Sourgeois, Germany and Milton Bonelli, United Kingdom

Open forum discussions with competent authority representatives and stakeholders from different EU countries

09:15 The updated EMA guideline on strategies to identify and mitigate risks in First-in-Human clinical trials with investigational medicinal products. 
Introduction by Ulrike Lorch, United Kingdom

Panel with representatives from EMA and Competent Authorities: Thomas Sudhop, Greet Musch, Milton Bonelli, David Jones, Kirsty Wydenbach

10:00 Prevention of over-volunteering in Europe: “How to get a European-wide acceptable system going?”
Introduction by Annick Peremans, Belgium

Panel with stakeholders from different EU countries: Barbara Schug, Annick Peremans, Peter Liedl

10:45 Break

Session 2: Scientific tools in early development of medicines to mitigate risk 
Chairs: Mike Hammond, United Kingdom and Yves Donazzolo, France

11:15 Can assessment of CNS target engagement in early development help to minimise risk? 
Philippe Danjou, France

11:40 Usefulness of physiology-based pharmacokinetics to mitigate risk? 
An Van Den Bergh, Belgium

12:05 Metabolomics and emerging applications in drug discovery and precision medicine. 
Elaine Holmes, United Kingdom

12:30 Innovative in-vitro models of toxicology assessments. 
Christopher Goldring, United Kingdom

13:00 Lunch and guided poster tour
Session 3: Innovative methods and imaging techniques in early medicines development – presentations from selection of submitted abstracts
14:30 Chairs: Luc Van Bortel, Belgium and Henri Caplain, France
15:45 Break

Session 4: Examples of innovation and risk management (Session organized by the AHPPI)
Chairs: Elizabeth Allen, United Kingdom and Stuart Mair, United Kingdom
Jorg Taubel, United Kingdom
16:35 Toxicity and dose escalation: progression rules in integrated protocols.
David Jones, United Kingdom
16:55 Examples of innovation and risk management: perspective from university and industry.
Alan Boyd, United Kingdom
17:20 Session summary and close
17:30 End of day 1

19:30 Reception and conference dinner at the Museum of London
Award ceremony for the best short presentation and best poster.

Day 2 Friday 19 May 2017

Session 5: Assessment and mitigation of risk in modern development strategies for paediatrics
Chairs: Ingrid Klingmann, Belgium and John van den Anker, USA / Switzerland
09:00 Microdosing: an opportunity for safer drug development in children?
Saskia De Wildt, The Netherlands
09:25 Oxford debate: “Too many PIPs and no adequate trials”
Introduced and moderated by Ingrid Klingmann, Belgium
Statement: “Paediatric medicines development should be limited to pharmacokinetic bridging trials”.
Pro: NN (to be confirmed)
Contra: Christoph Male, Austria
10:15 Break

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Parallel workshops:

10:45

1. How to use the results from non-clinical studies to better predict the risks in early phase clinical trials?
   *Roberto Gomeni, France and Stephanie Plassmann, Switzerland*

2. Modern drug development in oncology - How to successfully design the early phase trials?
   *Sylvie Rottey, Belgium and Heike Oberwittler, France*

3. Incident management in Phase I trials: what to do if things go wrong?
   *Katharina Erb-Zohar, Germany and Yves Donazzolo, France*

12:15 Lunch

Session 6: *Assessment and mitigation of risk in trials with biologicals*
   Chairs: *Barbara Schug, Germany and Jean-Louis Pinquier, France*

13:30 Keynote lecture on immuno-oncology - “How it all got started…“
   *Christian Blank, The Netherlands*

14:00 How to monitor and mitigate immunotoxicity during early phase clinical trials in oncology?
   *Ioannis Karydis, United Kingdom*

14:25 How to monitor and mitigate immunotoxicity during early phase clinical trials in inflammatory disease?
   *Ann Gils, Belgium*

14:50 How to monitor and mitigate immunogenicity during early phase clinical trials?
   *Geoff Hale, United Kingdom*

15:15 Panel discussion

15:45 Closing remarks

16:00 End of conference