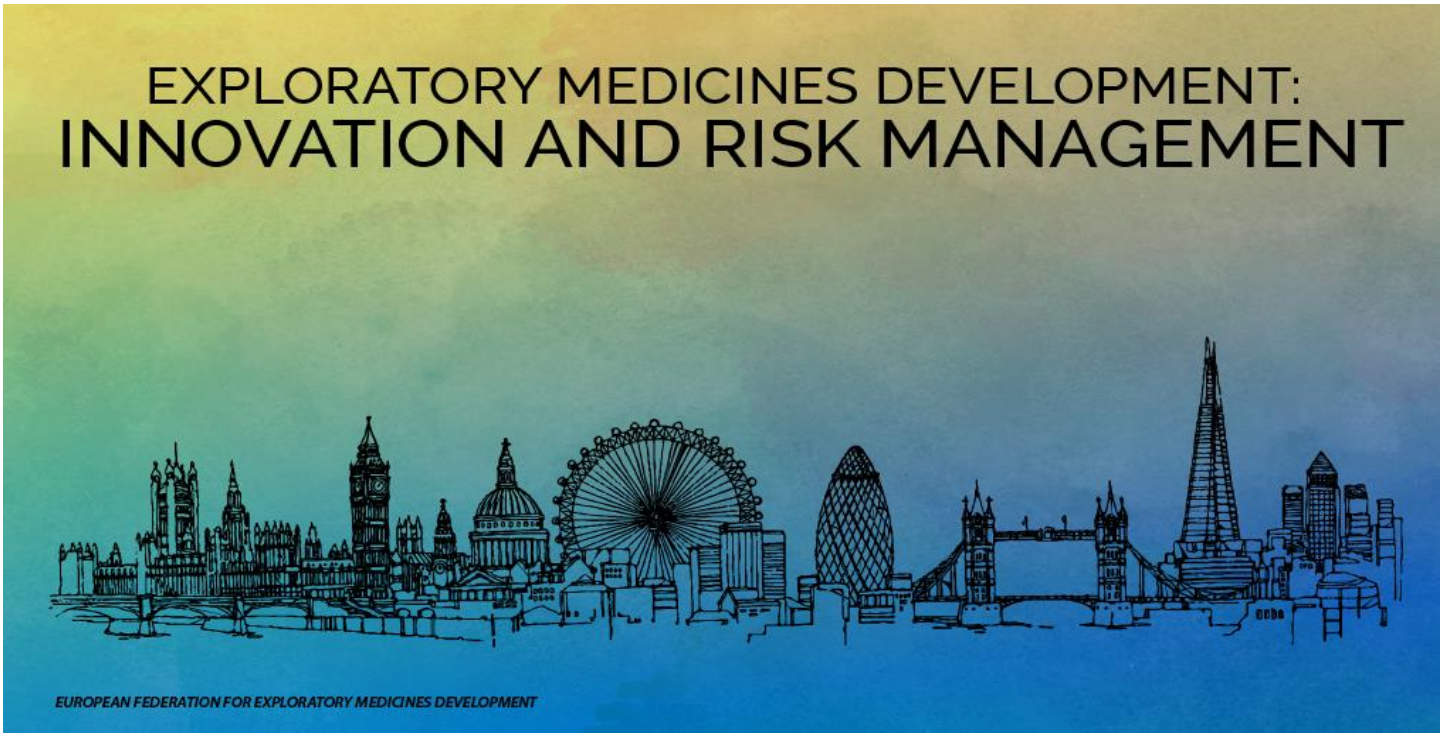
CONFERENCE PROGRAMME

18 – 19 May 2017



PROGRAMME COMMITTEE

AGAH, Germany: Dr Kerstin Breithaupt, Dr Ingrid Klingmann, Professor Hildegard Sourgens
AHPPI, UK: 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): Dr Tim Hardman, Dr Ulrike Lorch, Mr Steffan Stringer

CONFERENCE FACULTY

Professor Elizabeth Allen, Quintiles, UK
Dr Claire Ambery, GSK, UK
Professor Dr Christian Blank, Netherlands Cancer Institute, The Netherlands
Dr Milton Bonelli, European Medicines Agency (EMA), UK
Dr Bruno Boutouyrie, Novartis, Switzerland
Dr Malcolm Boyce, Hammersmith Medicines Research Ltd, UK
Professor Alan Boyd, Faculty of Pharmaceutical Medicine, UK
Dr Kerstin Breithaupt-Groegler, kbr – clinical pharmacology services, Germany
Dr Henri Caplain, Club Phase I, France
Professor François Chapuis, Lyon University Hospital, France
Dr Philippe Danjou, Biotrial, France
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
Mr Philippe Grosjean, Sanofi, France
Professor Geoff Hale, Freelance Scientist, UK
Dr Mike Hammond, Clinical Quality Management Solutions Limited, UK
Dr Tim Hardman, Niche Science and Technology, UK
Professor Elaine Holmes, Imperial College, UK
Dr Walter Janssens, Federal Agency for Medicines and Health Products, Belgium
Dr David Jones, Medicines & Healthcare products Regulatory Agency (MHRA), 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 Heike Oberwittler, Ipsen Innovation, France
Professor Marc Pallardy, Paris-Sud University, France
Ms Annick Peremans, Research Centre Aalst, Belgium
Dr Jean-Louis Pinquier, DECISIONS R&D consulting, 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
Dr An Van Den Bergh, Johnson & Johnson, Belgium
Dr Kirsty Wydenbach, Medicines & Healthcare products Regulatory Agency (MHRA), UK

PROGRAMME

Day 1 Thursday 18 May 2017

08:00 Registration

08:30 Welcome and Introduction to the 1st EUFEMED conference (*Jan de Hoon, Belgium)*

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

Session 1: Managing risks in early phase clinical trials
Chairs: *Hildegard Sourgens, Germany* and *Milton Bonelli, UK*

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, UK*

Panel with representatives from EMA and National Competent Authorities / Ethics Committees: *Milton Bonelli (UK), François Chapuis (France), Walter Janssens (Belgium), David Jones (UK), Thomas Sudhop (Germany), Kirsty Wydenbach (UK)*

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: *Milton Bonelli (UK), Malcolm Boyce (UK), Peter Liedl (Germany), Annick Peremans (Belgium), Barbara Schug (Germany)*

10:45 Break

Session 2: Scientific tools in early development of medicines to mitigate risk
Chairs: *Mike Hammond, UK* 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, UK

12:30 Lunch

13:15 Three guided poster tours chaired by

Henri Caplain, France and *Kerstin Breithaupt, Germany*
Tim Hardman, UK and *Yves Donazzollo, France*
Luc van Bortel, Belgium and *Hildegard Sourgens, Germany*

Session 3: **Innovative methods and imaging techniques in early medicines development – oral presentations from selection of submitted abstracts**
Chairs: *Luc Van Bortel, Belgium* and *Henri Caplain, France*

14:00	3.1	Activation of PAC1 by maxadilan: a new human target engagement biomarker *Linde Buntinx, Belgium*
14:15	3.2	Human challenge studies in healthy volunteers: Considerations for practical implementation. *Josué K Mfopou, Belgium*
14:30	3.3	Practical risk management in early phase clinical trials *Simon Coates, UK*
14:45	3.4	A pilot, phase Ib feasibility study of ARGX-110 in patients with nasopharyngeal carcinoma. *Sylvie Rottey, Belgium*
15:00	3.5	Presenting a decentralized, centrally governed, secure open source software solution for over-volunteering leveraging blockchain and biometrics. *Stuart Robertson, USA*
15:15		Break

Session 4: **Examples of innovation and risk management**
(Session organized by the AHPPI)
Chairs: *Elizabeth Allen, UK* and *Stuart Mair, UK*

15:45	Integrated protocols: from First-in-Human to Proof of Concept. *Jorg Taubel, UK*
16:05	Toxicity and dose escalation: progression rules in integrated protocols. *David Jones, UK*
16:25	Innovative in-vitro models of toxicology assessments *Christopher Goldring, UK*
16:45	Examples of innovation and risk management: perspective from university and industry. *Alan Boyd, UK*
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 oral presentations and best posters

Day 2 Friday 19 May 2017

Session 5: Assessment and mitigation of risk in modern development strategies for pediatrics
Chairs: *Ingrid Klingmann, Belgium*

09:00 Microdosing: an opportunity for safer drug development in children?
Saskia de Wildt, The Netherlands

09:25 Oxford Debate: Optimising PIPs through knowledge integration
Introduced and moderated by *Ingrid Klingmann, Belgium*
Motion: "Paediatric medicines development should be limited to pharmacokinetic bridging trials."

For the motion: *Claire Ambery, UK*
Against the motion: *Christoph Male, Austria*

10:15 Break

Parallel workshops:

10:45

1. How to use the results from non-clinical studies to better predict the risks in early phase clinical trials?
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*

13:50 Keynote lecture on immuno-oncology - "How it all got started…"
Christian Blank, The Netherlands

14:15 How to monitor and mitigate immunotoxicity during early phase clinical trials in oncology?
Ioannis Karydis, UK

14:40 How to monitor and mitigate immunotoxicity during early phase clinical trials in inflammatory disease?
Ann Gils, Belgium

15:05 How to monitor and mitigate immunogenicity during early phase clinical trials?

Geoff Hale, UK

15:30 Panel discussion

15:55 Closing remarks (*Hildegard Sourgens, Germany*)

16:00 End of conference