EUFEMED EUROPEAN FEDERATION FOR EXPLORATORY MEDICINES DEVELOPMENT

2nd EUFEMED Conference

The Changing Landscape of Early Medicines Development: Be Prepared!

15 - 17 May 2019 - Lyon, France

Programme Committee Members

Yves Donazzolo (CPI)
Henri Caplain (CPI)
Hildegard Sourgens (AGAH)
Ingrid Klingmann (AGAH)
Jan de Hoon (BAPU)
Sylvie Rottey (BAPU)
Steffan Stringer (AHPPI)
Jörg Täubel (AHPPI)
Mike Hammond (AHPPI)
Izaak den Daas (Associate Member)

Organisational Committee Members

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PRE-CONFERENCE WORKSHOPS

WEDNESDAY 15 MAY 2019	
Workshop 1: Modelling and simulations, including PBPK to improve the clinical development Chairs: Andreas Kovar, Germany and François Bouzom, Belgium	
11.00	Welcome and introduction by the Chairs Henri Caplain, France
11.15	**Principles of modeling and simulation including physiology-based pharmacokinetic (PBPK)** François Bouzom, Belgium
11:45	**A general in-silico framework for maximizing the benefit-risk ratio of a treatment** Roberto Gomeini, France
12.30	Lunch
13.15	**Simulation of first-in-human using an allometrically scaled population mechanistic TMDD model** Géraldine Ayral, France
13.45	**From phase I data to phase II trial design: simulation and extension of a population pharmacokinetic model** Pauline Traynard, France
14.15	**How PBPK modelling together with Bayesian statistics and targeted clinical data can be used to predict drug pharmacokinetics across patient populations?** Lars Kuepfer, Germany
14.45	**Various examples for the integration of cellular effect models from computational systems biology into whole-body PBPK models** Lars Kuepfer, Germany
15.15	Refreshment break
15.45	**Population-based and physiology-based PK models for drug-drug interaction trials and trials waiver** Kenichi Umehara, Switzerland
16.30	**Advance current PBPK model applications to support internal development and regulatory decisions** Maxime Le Merdy, Switzerland
17.00	**How to obtain biowaivers for clinical trials using PBPK, two case studies** Maxime Le Merdy, Switzerland
18.00	**What did we learn?** Open forum discussion with speakers and participants
18.15	End of Workshop 1

Workshop 2: Early clinical development of biologics – what is so different about it? Chairs: Hildegard Sourgens, Germany and Jan de Hoon, Belgium	
11.00	Welcome and introduction by the Chairs
11.10	**New therapeutic concepts** Philip Barrington, UK
12.45	Lunch
13.30	**What is different in PK of biologicals** Stephan Glund, Germany
15.00	Refreshment break
15.15	**How to approach PD and safety** Meagan O'Brien, US
16.45	**ADAs / Immunogenicity** Ann Gils, Belgium
17.45	**What did we learn?** Open forum discussion with speakers and participants
18.15	End of Workshop 2

18.15-19.30	**Welcome Reception – Exhibition Area, Centre de Congrès de Lyon**

FINAL CONFERENCE PROGRAMME

THURSDAY 16 MAY 2019	
08.00	Registration
08.45	Welcome and Introduction Hildegard Sourgens, Germany
Session 1: Current and future options for virtual trials in early medicines development Chairs: Eric Legangneux, France and Georg Wensing, Germany	
09.00	Keynote lecture **The potential role of virtual trials in early medicines development: Beyond pharmacology to mechanisms** Adriano Henney, UK
09.20	**The in silico paradigm: understanding the potential of mechanistic models and their limitations, adapting organizations and building the necessary expertise** François-Henri Boissel, France
09.40	**The virtual physiological human – impact on early medicines development** Stig Omholt, Norway
10.00	**Open forum discussion** With session chairs, speakers, and Ingrid Klingmann, Belgium
10.45	Refreshments and Exhibition Viewing
Session 2: Trends and innovation Chairs: Henri Caplain, France and Yves Donazzolo, France	
11.15	**#WeAreNotWaiting for better diabetes care** Andrew Warrington, Switzerland
11.45	**Engineering allogeneic immune cells to generate off-the-shelf CAR T-cell immunotherapies** Roman Galetto, France
12.15	**Translation of gene therapeutics in neurological and neuromuscular diseases** Brian K. Kaspar, Switzerland
12.45	Lunch and Exhibition Viewing
Session 3: Guided poster tours and selected oral presentations Chairs: Sylvie Rottey, Belgium and Tim Hardman, UK Selection of posters: Sylvie Rottey (Chair), Jan de Hoon, Tim Hardman, Henri Caplain, George Wensig and Bob Wilffert	
13.45	**Guided poster tours**
14.15	**Oral presentations** (five presentations selected from submitted posters) 3.1: **Diurnal and racial variance of white blood cell parameters in early phase clinical trials: a retrospective analysis of pooled data from multiple phase I trials** Simon Coates, UK 3.2: **Do we need pharmacokinetic data during each data review meeting in adaptive first-in-human trial? From guideline to practice** Nariné Baririan, Belgium 3.3: **Impact of cholinergic tone on the binding of PET tracer [11C]MK-6884, a positive allosteric modulator of M4 acetylcholine receptor in monkeys and healthy elderly volunteers** Inge De Lepeleire, Belgium 3.4: **Outcome of patients participating in early phase oncology trials at the Drug Research Unit Ghent (D.R.U.G.), Belgium** Brant Delafontaine, Belgium 3.5: **Volumetric Absorptive Microsampling (VAMS) for Blood Collection in Clinical Studies of Padsevonil** Hugues Chanteux, Belgium

15.30	Refreshments and Exhibition Viewing
Parallel Breakout Sessions	
16.00-17.30	1. **Digital support to study performance in early phase development – from recruitment to remote data collection** Robert Rissmann, The Netherlands and Ingrid Klingmann, Belgium
	2. **Lay summary requirements – consequences for Phase I trials** Kerstin Breithaupt, Germany and Leonie Leithold, Germany
	3. **Transparency requirements for Phase I trials in times of transition** Izaak den Daas, Gerard Koëter and Sander van den Bogert, The Netherlands
	4. **What is acceptable/ethical to test in healthy subjects?** Sylvie Rottey, Belgium and Jan de Hoon, Belgium
17.30	End of Day 1
19.30-22.30	**Conference Dinner – Hèrmes River Boat**

FRIDAY 17 MAY 2019	
Session 4: Update on regulatory considerations for early clinical development (including Brexit) Chairs: Mike Hammond, UK and Ingrid Klingmann, Belgium	
09.00	**MHRA perspective** Ian Rees, UK
09.20	**EMA perspective** Fergus Sweeney, The Netherlands
09.40	**Industry perspective** Nick Sykes, Pfizer, UK
10.00	Round table discussion
10.30	Refreshments and Exhibition Viewing
10.45-12.15	**Parallel break-out sessions** The same workshops as those presented on the first day will be repeated
12.15	Lunch and Exhibition Viewing
Session 5: How to be prepared Chairs: Jörg Täubel, UK and Jan de Hoon, Belgium	
13.15	**Phase I trials in patients: new approaches and designs in Oncology** Nuria Kotecki, Belgium
13.45	**Challenges in exploratory clinical research** Maarten Van den Boer, Belgium
14.15	**Current perspectives on digital biomarker development in early clinical research** Virginia Parks, USA
14.45	**Closing remarks – How to be prepared!** Yves Donazzolo, France
15.00	End of Conference