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:

- Yves Donazzolo (CPI)
- Henri Caplain (CPI)
- Steffan Stringer (AHPPI)
- Hildegard Sourgens (AGAH)

PROGRAMME

Day 1: 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: What is the role of virtual trials in early medicines development – outline, prerequisites and impact
Adriano Henney, UK

09:30 The virtual physiological human – impact on early medicines development
Stig Omholt, Norway

10:00 Open forum discussion with representatives from the European Commission (Christina Kyriacopoulou, UK, invited) and Experts in the field (François-Henri Boissel, France and Ingrid Klingmann, Belgium)

10:45 Break

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*

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, Bob Wilffert, Jörg Täubel*

13:45 Guided poster tours

14:15 Oral presentations (five presentations will be selected from submitted posters)

15:30 Break

Parallel Break-out Sessions:

16:00 – 17:30

1. Digital support to study performance in early phase development – from remote visit conduct to biomarker apps
   NN
2. Lay summary requirements – consequences for Phase I trials
   Kerstin Breithaupt, Germany and *Thomas Schindler, Germany*
3. Transparency requirements for Phase I trials in times of transition
   Izaak den Daas, NL and NN, NL
4. What is acceptable/ethical to test in healthy subjects?
   Jan de Hoon, Belgium and *Sylvie Rottey, Belgium*

17:30 End of Day 1

19:30 Conference Dinner

Day 2: 17 May

Session 4: The impact of Brexit on early clinical development in Europe
Chairs: *Mike Hammond, UK* and *Ingrid Klingmann, Belgium*

09:00 MHRA perspective
Samantha Atkinson, UK

09:20 EMA perspective
EMA representative confirmed (NN), Fergus Sweeney (invited)

09:40 Industry perspective
Paer Tellner, Germany (Invited)

10:00 Round-table discussion

10:30 Break

10:45 – 12:15 **Parallel break-out sessions:** the same workshops as those presented on the first day will be repeated.

12:15 Lunch

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 Multinational, multicenter Phase I trials – operational challenges,
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

Preconference 1-day workshops : 15 May 2019

Workshop 1: **Trial simulation and basic tools**

Chairs: Andreas Kovar, Germany and *Henri Caplain, France*

11:00 Welcome and Introduction by the Chairs

11:10 Basic principles of physiology-based PK
Basic principles of modeling and simulation

12:45 Lunch

13:30 Trial simulation for dose prediction of clinical trials of later phases

15:00 Break

15:15 Trial simulation for waiving clinical trials:

- Physiology-based PK models replacing drug-drug interaction trials
- Renal and hepatic impairment
- Genetic variations (personalized medicine)
- Age groups

16:45 Training software for virtual trials

17:45 What did we learn? / Open forum discussion with all speakers and participants

18:15 End of Workshop

Speakers :

Roberto Gomeni, France
Bernard Orlandini, France
Andreas Kovar, Germany

Capacity: 50 - 60 participants

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 *Stefan Glund, Germany*
15:00	Break
15:15	How to approach PD and safety *Angus MacDonald (invited), US*
16:45	ADAs / Immunogenicity *Ann Gils, Belgium*
17:45	What did we learn? / Open forum discussion with all speakers and participants
18:15	End of Workshop

Capacity: 50 - 60 participants