

DAY 2 12 APRIL 2013

**Session 4: Innovative approaches to Proof-of-Concept**

*Chairs: J. Taubel, London (UK)  
O van Schoor, Antwerp (Belgium)*

9:00 **Rapid transition from bench to bedside:**  
An overview; what is new, what has proven its value, what are the latest trends in translational medicine  
*J. Theis, Bergisch-Gladbach (Germany)*

9:30 **What contribution can we expect from pharmacogenetics; how will this transform the design and endpoints of clinical studies?**  
*TBA*

10:00 **Cutting edge developments: biomarker qualification as an indicator for clinical endpoints and their role in setting an optimal biologic dose**  
*TBA*

10:30 **Break**

**11:00 Parallel Workshops**

WS1-WS4 **Repetition of Day 1**

WS1 **Cardiac safety, QT assessment**  
*B. Mendzelevski, London (UK)  
J. Taubel, London (UK)*

WS2 **PK/PD modeling**  
*R. Gomeni, La Fouillade (France)*

WS3 **MTD calculation based on preclinical assessment**  
*B. Reignier, Basel (Switzerland)  
F. Vanderhande, Brussels (Belgium)*

WS4 **Adaptive study design in early phase clinical research**  
*E. Godfrey, London (UK)  
U. Lorch, London (UK)*

WS5.b **Pain Models**  
*Ph. Danjou, Paris (France)*

12:30 **Lunch Break**

**Session 5: Strengthening European Human Pharmacology for the Early Development of Modern Therapies**

*Chairs: U. Lorch, London (UK)  
H. Sourgens, Munich (Germany)*

13:30 **Open Forum Discussions:**  
**A critical review of the proposed EU Clinical Trial regulation**  
*G. Musch or W. Janssens  
Federal Agency for Medicines and Health Products, Brussel (Belgium)*

14:15 **Need for a uniform European registration system for volunteer participation?**  
*A. Peremans, Antwerp (Belgium)*

15:00 **Risk adapted approaches and clinical trial notification scheme**  
*E. Godfrey, London (UK)*

15:45 **Closing remarks by Club Phase I**

16:00 **End of Conference**

**Venue:** Hotel Sophia Country  
3550 Route des Dolines BP 15  
06410 Biot-Sophia Antipolis (FRANCE)  
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**Fees:**

Member of*	380 €
Non-Members	430 €
Junior Scientist	270 €
reduction early bird	- 50 €

(registration prior to 31 January 2013)

\*CP1: <http://www.clubphase1.com>  
AGAH: <http://www.agah.info>  
BAPU: <http://www.bapu.be>  
AHPPI: <http://www.ahppi.org.uk>

Start Online-Registration and Hotel reservation by:  
[http://l.hh.de/JointConference\\_2013](http://l.hh.de/JointConference_2013)

# CLUB PHASE 1



## Joint Conference of European Human Pharmacological Societies

## EARLY CLINICAL UTILITY ASSESSMENT OF NEW MEDICINES IN DEVELOPMENT



Photo: Marcus Augustine

11 & 12 April 2013  
Nice Sophia Antipolis, FRANCE

First Announcement

Dear Colleague

2013 is a special year for CLUB PHASE 1, as this year it celebrates its 20<sup>th</sup> anniversary, welcoming fellow European colleagues of AGAH, BAPU and AHPPI to the stunning region of NICE, where we will join forces to offer our second joint meeting.

It will be a great opportunity to share our views on the challenges currently being faced by the Early Clinical Development and Clinical Pharmacology.

The meeting will focus on Early Clinical Utility Assessment of new medicines and how early development should be conducted to optimize the challenging process of reaching efficient and early go/no go decisions.

After review of some “historical” cases, this meeting will update attendees on new translational tools and innovative approaches, and will highlight the need for a strong presence of European Human Pharmacology in Early Development.

We hope that the plenary lectures and workshops will provide ample opportunity to discuss ideas, strategies, methods, technology and experience in early clinical development.

Looking forward to welcoming you in Sophia Antipolis, France.

Doctor Yves Donazzolo  
Club Phase 1 President

## DAY 1 11 April 2013

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- 08:00 Registration
- 08:30 Welcome and introduction to the Joint Conference of Club Phase I, AGAH, BAPU and AHPPI
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### Session 1: Lessons learned from late phase failures and successes

- Chairs: Y. Donazzolo, Lyon (France)  
M. Raghoobar, Antwerp (Belgium)*
- 8:45 Lessons learned from Rimonabant and other CB1 blockers: did we try to crack a nut with a sledgehammer?  
*R. F. Witkamp, Wageningen (The Netherlands)*
- 9:15 Clinical Pharmacology and Clinical Utility of Abiraterone Acetate  
*E. Mannaert, Beerse (Belgium)*
- 9:45 The role of Phase I in the quest for “good” cholesterol – failure of the CETP modulator Dalcetrapib  
*M. Derks, Basel (Switzerland)*
- 10:15 Break
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### Session 2: New translational tools and methodologies

- Chairs: A. Patat, Rennes (France)  
M. Hammond, Slough, Berkshire (UK)*
- 10:45 Usefulness of modeling and simulations in drug development  
*E. Pigeolet, Basel (Switzerland)*
- 11:15 Pharmacometrics: a new tool for optimizing early drug development in oncology  
*R. Gomeni, La Fouillade (France)*
- 11:45 New biomarkers for drug-induced liver injury: first<sup>2</sup> insights from clinical quantification  
*M. Merz, Basel (Switzerland)*
- 12:15 Quantification of EEG: pre-competitive consortium on the use of EEG as a CNS biomarker  
*Ph. Danjou, Paris (France)*
- 12:45 Lunch Break
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### 14:15 Parallel Workshops

- WS1 Cardiac safety, QT assessment  
*B. Mendzelevski, London (UK)  
J. Taubel, London (UK)*
- WS2 PK/PD modeling  
*R. Gomeni, La Fouillade (France)*
- WS3 MTD calculation based on preclinical assessment  
*B. Reignier, Basel (Switzerland)  
F. Vanderhande, Brussels (Belgium)*
- WS4 Adaptive study design in early phase clinical research  
*E. Godfrey, London (UK)  
U. Lorch, London (UK)*
- WS5.a Suicidality assessment  
*E. Legangneux, Basel (Switzerland)*

15:45 Break

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### Session 3: Training and education in early clinical drug development

- Chairs: K. Breithaupt-Grögler, Frankfurt (Germany)  
J. de Hoon, Leuven (Belgium)*
- 16:15 European post-graduate training in pharmaceutical medicine and drug development  
*I. Klingmann, Brussels (Belgium)*
- 16:35 Human Pharmacology courses: the UK experience  
*J. Posner, London (UK)*
- 16:55 Open Forum Discussion: “Diploma-level training for Phase 1 Investigators – need or nice-to-have?”  
*TBA*
- 17:15 End of Sessions on Day 1
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- 19:30 Conference Dinner