

Thursday - April 26, 2007

08.30 **Registration and coffee**

09.00 Opening remarks

Presidents AGAH and Club Phase I

Session I Current approaches in human pharmacology

Chair: Y. Donazzolo, Gières, T. Thomsen, Andernach

09.05 Pharmacokinetics and bioavailability: Examples from various body fluids *W. Cavello, Monheim*

09.40 Tolerability and safety: Predictability of QT prolongation in healthy subjects from preclinical experiments *H. Caplain, Paris*

10.15 Dose/concentration-effect relationship: Biomarkers in CNS drug development - effects of opioid analgesics
F. Fliegert, Aix-la-Chapelle

10.50 **Coffee break**

11.15 **Parallel workshops:**

- An introduction to state of the art pharmacokinetics
W. Cavello, Monheim
- PK and PD as predictors of a clinical effect
J. Grevel, Verona
- Need for and approaches to a European trial subjects database
B. Schug, Oberursel, R. Schäfer, Frankfurt, A. Peremanns, Brussels, Y. Donazzolo, Gières, T. Thomsen, Andernach
- Designs of human pharmacology trials for paediatric populations
E. Jacqz-Aigrain, Paris, H. Seyberth, Landau
- Current regulatory developments relevant to human pharmacology in the EU
I. Klingmann, Brussels, C. Schneider, Langen

12.30 **Lunch break and Poster Session**

Session II What is human pharmacology expected to deliver in the future?

Chair: K. Breithaupt-Grügler, Frankfurt, A. Patat, Rennes

14.00 From understanding the disease to implementing the diagnostic biomarker and the effective treatment—practical examples
S. Stürzebecher, Aix-la-Chapelle

14.35 Development of meaningful interaction studies for combination therapies
J. van Gerven, Leiden

15.10 Imaging techniques in the early development of new compounds
P. Danjou, Paris

15.45 **Coffee break**

16.00 Round table discussion

Chair: I. Klingmann, Brussels, I. Paty, Paris

Will human pharmacology be needed to develop individualized treatments?

Participants: D. Austin, London, H. Caplain, Paris, T. Sudhop, Bonn, S. Stürzebecher, Aix-La-Chapelle, M. Zühlsdorf, Basle

17.15 End of Day I

18.30 **Conference Dinner Event**



Friday - April 27, 2007

Session III Challenges and limitations of human pharmacology

Chair: L. Tritsman, Brussels, J. van Gerven, Leiden

08.30 Human pharmacology for biologicals—first into man
D. Austin, London

09.00 Genotyping: A reliable predictor for safety and tolerability?
M. Schwab, Stuttgart

09.30 Interpretation of early safety signals
M. Sibille, Lyon

10.00 **Coffee break**

10.30 **Parallel workshops:**

- Microdosing: myths and reality; scientific, regulatory and financial perspectives
J. de Hoon, Leuven, D. Pegg, Ann Arbor, C. Schneider, Langen, C. Garner, Haslington
- Predictability of pharmacological methods
J-L. Pinguier, Paris
- Biomarkers in specific areas
M. Zühlsdorf, Basle
- Sustainability of the pharmaceutical development pipeline: methods, facts and perspectives
W. Seifert, Berlin
- Do population kinetics work without dense data sampling?
N.O. Hoem, Hamburg

12.00 **Lunch break and Poster Session**

Session IV Getting fit for the future of human pharmacology

Chair: H. Caplain, Paris, C. Hinz, Rheinau

13.30 Scientific requirements: Perspective of an editor for an international clinical pharmacology journal
U. Fuhr, Cologne

14.00 Oxford debate on how to establish tolerability and safety—MTD versus pharmacological activity
M. Sibille, Lyon, J. van Gerven, Leiden

14.45 New regulatory requirements for first into man studies in Germany and France
T. Sudhop, BfArM, Bonn, D. Tremblay AFSSAPS, Paris

15.45 Closing remarks
H. Fuder, Hamburg

Positioning Human Pharmacology for the Future

Second Joint Annual Meeting Club Phase I and AGAH

This second joint meeting of Club Phase 1 - the French Association of Early Human Drug Development — and AGAH — the German Association for Applied Human Pharmacology - addresses a vital question: „How to position human pharmacology for the future?“

Which role can and should human pharmacology play in the development of new classes of drugs and biologicals? This meeting will attempt to find answers to these questions and also to highlight technical-, safety- and regulatory issues impacting on clinical development.

AGAH and Club Phase 1 are delighted to welcome our Belgian Colleagues from BAPU to this meeting and are looking forward to their scientific contributions and collaboration. This will certainly foster the widespread mutual interest for a pan European collaboration of human pharmacologists

CONGRESS INFORMATION

Date	April 26 and 27, 2007
Venue	MARITIM HOTEL BAD HOMBURG Kurhaushotel/Kongresszentrum Ludwigstraße 3 61348 Bad Homburg vor der Höhe Germany
Telephone	+49 (0)6172 660-0
Fax	+49 (0)6172 660-100
Registration	INTERCOM Dresden Antje Blömeke Zellescher Weg 3 01069 Dresden Germany
Telephone	+49 (0)351 4633 3014
Fax	+49 (0)351 4633 7049
E-mail	abloemeke@intercom.de
Homepage	www.agah-web.de
Fees	250,00 € Member (early registration) 275,00 € Member 275,00 € Nonmember (early registration) 300,00 € Nonmember 200,00 € Junior Scientist 125,00 € Junior Poster (Member) 150,00 € Junior Poster (Nonmember) 200,00 € Day Ticket 275,00 € Industry Exposition Staff
	Early bird reductions applied for registration up to January 31, 2007.
	Fees include admission to all sessions, lunches and coffee breaks.
Accommodation	A number of rooms at special discounted rates are available at the Venue.



AGAH

2nd Joint Annual Meeting 2007



Positioning Human Pharmacology for the Future

April 26 and 27, 2007

Bad Homburg v.d.H., Germany