AGAH

Arbeitsgemeinschaft für angewandte Humanpharmakologie (AGAH) e.V.

This first joint meeting of AGAH—the German Association for Applied Human Pharmacology - and the Club Phase I - the French Association of Early Human Drug Development - focuses on the scientific and regulatory challenges of early drug development. It will address technical, safety and regulatory issues impacting on global clinical development plans. In combining the congress concepts of the two sister organizations this meeting offers a wide array of both plenary lectures and workshops suitable both for newcomers and more experienced members of the scientific community. Strasbourg, the venue for this international congress was chosen as a European Capital and for its role as a bridge between France and Germany and, obviously, for the many attractions the region has to offer.

Club Phase I

AGAH - Annual Meeting 2005 - Club Phase 1
Early Drug Development — Scientific and Regulatory Challenges

Thursday, 17 March 2005

08.30	**Registration and coffee**
09.15	Opening remarks *G. Mikus (AGAH) and Y. Donazzolo (Club Phase 1)*
Session I	**Why do we need Phase 1 studies?** *Chair: H Fuder and H Caplain*
	Plenary lectures
09.30	Is Phase I useful? *W. Seifert, Berlin*
09.55	Healthy volunteers or patients as target population in Phase I trials *H. Fuder, Berlin*
10.20	When to stop dose escalation: MTD or MLD or ...? *H. Caplain, Paris*
10.45	Coffee break
	Parallel workshops
•	Design aspects of Phase I studies and recruitment bias during early development *M. Buise, Brussels ; B. Boutouyrie, Basel, G. Nemitz, Biberach*
•	Women in Phase I studies *C. Klipping, Nijmegen ; D. HegerMahn, Berlin ; K. Breithaupt-Grögler, Frankfurt*
•	Pediatric clinical trials *E. Autret-Leca, Paris*
•	Special populations *B. Schug, Oberursel*
•	New drugs in oncology *JL. Pinquier, Paris ; P. Squiban, Strasbourg*
12.30— 14.00	Lunch break

Session II	**Implications of the new EU-directive on clinical trials** *Chair: Y Donazzolo and R Schulz*
	Plenary lectures
	Experience reports from the first year of working within the new regulatory environment:
14.00	France *A. Patat, Paris*
14.15	Germany *R. Frey, Wuppertal*
14.30	United Kingdom *S. Warrington, London*
14.45	The Netherlands *J. van Gerven, Leiden*
15.00	Central Europe *C. Reh, Berlin*
15.15	Comparison between European countries *A. Patat, Paris*
15.45	Coffee break
16.00 - 17.15	**Round table discussion** Chair: *I Klingmann, Brussels*
	What is going well within the EU directive? Necessary improvements? ICH guideline for all? What do clinical researchers require from the EU directive in 2010? *C. Belorgey, Paris ; G. Schwarz, Bonn ; F. Chapuis, Lyon ; T. Sudhop, Bonn ; B. Lehmann, Brussels ; A. Patat, Paris ; R. Frey, Wuppertal ; S. Warrington, London ; J. van Gerven, Leiden ; C. Reh, Berlin*

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Session III	**Safety issues in Phase I trials** Chair: *M Sibille, J van Gerven*
08.30	Is Phase I safe? *M. Sibille, Lyon*
09.00	First dose and dose escalation *B. Reigner, Basel*
09.30	Allometric scaling *G. Sanderink, Paris*
10.00—10.30	Coffee break
10.30 - 12.00	**Parallel workshops:**
	• QTc: Predictability, science, regulations *M. Drici, Nice ; P. Maisonblanche, Paris*
	• Predictability of toxicity, population, CNS markers *J. van Gerven, Leiden*
	• Biotech products: Predictability from preclinical data *M. Zühlsdorf, Wuppertal ; G. Lemm, Leverkusen ; P. Guillet, Paris*
	• Bridging the tolerability gap between healthy volunteers and patients *H. Allain, Rennes ; U. Feifel, Biberach*
	• Safety guidelines *D. Sallieres, Paris*
12.00—13.30	Lunch break
Session IV	**New tools in early drug development** *Chair: G Mikus and P Rosenzweig*
13.30	When and how do PK/PD modelling and simulations make sense in early development? *E. Fuseau, Aix-en-Provence*
14.00	Informed consent process in pharmacogenomic studies (Germany, France, international views) *KL. Rost, Berlin*
14.30	Imaging in early drug development *D. Brooks, London*
15.15	Using proteomics to follow response to novel therapies *B. Acres, Strasbourg*
15.45	Closing remarks *JL. Imbs, Strasbourg*

Congress Information

Date 17 and 18 March 2005

Venue
Hotel Sofitel
4 Place Saint-Pierre-le-Jeune
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Registration
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Fees

225 €	Members of AGAH and CP1, and full-time academics
250 €	Non members
-25 €	Additional discount for registrations received before 16 December 2004

Fees include admission to all sessions, lunch and coffee breaks

Accommodation
A number of rooms at special discounted rates are available at the Venue and other Accor Group Hotels within easy walking distance. See the homepage for details.

Please make your own reservations early.

First Joint Annual Meeting 2005 AGAH and Club Phase 1

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Joint Annual Meeting 2005
AGAH (Germany)
Club Phase I (France)

Early Drug Development

Scientific and Regulatory Challenges

Club Phase I

Second Announcement