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**Session 3: FAST TRACK DEVELOPMENT – HAS THE CONCEPT WORKED, AND WHEN IS IT REALLY FEASIBLE?**

Chair: *Ulrich Feifel, Thomas Sudhop*

16:30 The Regulatory Perspective:  
What has Worked?

*Birka Lehmann, Bonn*

17:00 The Clinical Perspective:  
Experiences and Tools for Fast Track  
Developments

*Fritz Bühler, Basel*

17:30 End of Sessions on Day 1

19:30 **Conference Dinner**

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**TUESDAY, 23 FEBRUARY 2010**

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**Session 4: SCIENCE-DRIVEN REGULATION VERSUS TICKBOX APPROACH: APPLIED HUMAN PHARMACOLOGY IN SPECIAL POPULATIONS**

Chair: *Barbara Schug, Christian Hinze*

9:00 Introductory Remarks from the Chair

9:15 Applied Human Pharmacology in Children:  
From Past to Present

*Matthias Schwab, Stuttgart*

9:45 Paediatric Investigational Plan (PiP):  
Clinical Impact vs. Effort?

*Angelika Joos, Brussels*

10:15 Renal Impairment: From Dettli to Guideline:  
What Can We Learn?

*Meinolf Wonnemann, Erfurt*

**10:45 - 11:15 Coffee Break**

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**Online registration and hotel reservation:**

<http://www.intercom-dresden.de/agah2010/>

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**Session 5: TOOLBOX IN CLINICAL PHARMACOLOGY – PAST, PRESENT AND FUTURE**

Chair: *Torben Thomsen, Michael Zühlsdorf*

11:15 Today's Value of Population Pharmacokinetics

*Hans-Günter Schäfer, Biberach*

11:45 Biomarker: Clinical Validation for Intended Use

*Joop van Gerven, Leiden*

12:15 The Value of Pharmacodynamic Models and  
Go / No Go Criteria During Clinical Drug  
Development

*Georg Wensing, Wuppertal*

**12:45 – 13:45 Lunch Break**

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**Session 6: STRATEGIES FOR CLINICAL DRUG DEVELOPMENT IN THE FUTURE - APPLIED HUMAN PHARMACOLOGY 2.0**

Chair: *Fritz Bühler, Matthias Schwab*

13:45: Key-note Speech

*Adam Cohen, Leiden*

Panel Discussion

*F. Bühler, A. Cohen, M. Schwab, T. Sudhop,  
J. van Gerven, G. Wensing*

14:45 Closing Remarks

*Torben Thomsen, Andernach*

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**Venue:** Hotel Hafen Hamburg  
Seewartenstrasse 9, D-20459 Hamburg  
Phone: +49 (40) 311130

**Date:** Sunday, 21 Feb to Tuesday, 23 Feb 2010

**Conference fees:**

340,00 € members of AGAH, CPI, AHPPI,  
BAPU, and SPM

400,00 € non-members

250,00 € junior scientists

200,00 € day ticket

Titelbild: ©Hotel Hafen Hamburg, mit freundlicher Genehmigung



Arbeitsgemeinschaft  
für angewandte  
Humanpharmakologie e.V.

Association for Applied  
Human Pharmacology

20<sup>th</sup> Annual Meeting

**20 Years of Applied Human Pharmacology  
in Clinical Drug Development – Lessons  
Learned and Translation to Future Needs**



21 - 23 February 2010, Hamburg, Germany

**Programme**

## TWENTY YEARS OF APPLIED HUMAN PHARMACOLOGY IN CLINICAL DRUG DEVELOPMENT – LESSONS LEARNED AND TRANSLATION TO FUTURE NEEDS

To foster the creation of an association for applied human pharmacology, a group of human pharmacology experts working in Phase 1 Units in Industry and CROs organised a first conference in 1990 to exchange information and experience on how to perform human pharmacology trials according to the then newly established GCP principles and to enable faster drug development. This led to the foundation of AGAH (Association For Applied Human Pharmacology) which became incorporated in 1991, creating a lot of enthusiasm resulting every year in an interesting programme for the annual meetings. Thus, 2010 will mark the 20<sup>th</sup> AGAH Annual Meeting.

This is an excellent opportunity to critically review the progress made since, the lessons learned, as well as the potential to translate this knowledge into strategies and tools to successfully manage the forthcoming challenges in human pharmacology: drugs with new mechanisms of action, personalised therapies, higher pressure to achieve better predictability of a molecule's suitability for further development, shorter development times and globalisation of trial performance.

This conference will give you the opportunity to critically review current and past approaches to drug development, learn about experiences and practical aspects of human pharmacology, to discuss strategies and up-to-date tools for further improvement of clinical development in special populations, difficult pharmacokinetic conditions and an ever-changing regulatory environment.

## SUNDAY, 21 FEBRUARY 2010

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### 15:00 – 18:00 TRAINING SESSION (in German)

#### “Zielstellungen und Studienkonzepte in der klinischen Entwicklung (Wolfgang Timmer, Mannheim)

Übersicht über Studienarten, Studiendesigns, Zielkriterien, Mechanismen der Risikosteuerung und Elemente eines effizienten Projektmanagements“

*Veranstaltungsort: Hotel Empire Riverside  
Unkostenbeitrag: € 40,00 für Nichtmitglieder.*

### 19:00 AGAH General Assembly

## MONDAY, 22 FEBRUARY 2010

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08:30 Registration

09:00 Opening remarks  
*Ingrid Klingmann, Brussels*

### Session 1: PAST AND FUTURE CHALLENGES FOR APPLIED HUMAN PHARMACOLOGY

*Chair: Kerstin Breithaupt-Grögler,  
Jens Rengelshausen*

9:10 Solved Problems and Unsolved Challenges in Applied Human Pharmacology  
*Hildegard Sourgens, Munich*

9:40 The Changing Regulatory Requirements for Applied Human Pharmacology  
*Thomas Sudhop, Bonn*

10:10 Applied Ethics and Societal Aspects in Applied Human Pharmacology  
*David Haery, Bern*

10:40 Health Economics in Early Clinical Drug Development  
*Clemens Troche, Schwäbisch Hall*

11:10 – 11:40 Coffee Break

### Session 2: POX: POM, POP OR POC?

*Chair: Thomas Gramatté, Wolfgang Timmer*

11:40 From PD Models to PoX:  
Changing Terms or Mindset?  
*Michael Zühlsdorf, Darmstadt*

12:10 Lessons Learned (practical example)  
*Pierre Laurent-Puig, Paris*

12:40 Phase I, Ib, IIa, IIb, etc. - Is this way of thinking still appropriate?  
*Robert Hermann, Radolfzell*

13:10 – 14:30 Lunch

### 14:30 – 16:00 PARALLEL WORKSHOPS

WS 1 Cultural differences in GCP perception  
*Ilufredo (Fred) Tantoy, San Francisco*

WS 2 Modern Strategies for the Development of Generic Drugs:  
a) Locally Acting / Locally Applied Drug Products: A Playing Field for Human Pharmacologists?  
*Barbara Schug, Oberursel*

WS 3 Modern Strategies for the Development of Generic Drugs:  
b) Highly Variable Drugs: Sources of High Variability and Solutions to Overcome Problems in Bioequivalence Assessment“  
*Henning Blume, Oberursel/Germany,  
Jan Welink, The Hague/The Netherlands*

16:00 – 16:30 Coffee Break

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This meeting is accredited by the LÄK Hamburg, participants will be awarded 18 'Fortbildungspunkte'.

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