
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**

TUESDAY, 23 FEBRUARY 2010

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

Online registration and hotel reservation:

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

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

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

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

20th 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 20th 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

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

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

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