FRIDAY, 02 MARCH 2012

Session 4 **Subject stratification in drug development – getting it right?**

Chairs *Jens Rengelshausen, Jörg Täubel*

09:00 Chairman's introduction: Concept and impact of stratified medicine

09:10 Implementation of stratification throughout drug development – examples from oncology
Michael Zühlsdorf, Darmstadt

09:30 Personalised medicine: A new challenge for applied human pharmacology?
Jochen Theis, Bergisch-Gladbach

09:50 Roundtable discussion: When and how shall we use stratification?

10:20 Chairman`s summary and outlook: The future of stratified medicine

10:30-11:00 Break

Session 5 **Population aspects in oncology studies**

Chairs *Andreas Kovar, Barbara Schug*

11:00 BE and ADME studies in oncological patient populations
Barbara Schug, Oberursel

11:30 Drug-drug-interaction studies in oncology – a regulatory perspective
Jutta Heßling, Bonn

12:00 Clinical relevance of drug-drug interactions in oncology
Salah-Eddin Al-Batran, Frankfurt am Main

12:30-13:30 Break

Session 6 **Proof-of-Mechanism (PoM) / Proof-of-Concept (PoC) package**

Chairs *Thomas Sudhop, Wolfgang Timmer*

13:30 Practical examples of PoM studies in healthy subjects
Matthias Grossmann, Berlin
Klaus Francke, London

14:00 Suitable patient populations and study designs for rapid PoC
Anton Drollmann, Basel

14:30 How predictive is PoC for therapeutic success of the new drug?
Joop van Gerven, Leiden

15:00 Closing Remarks

INFORMATION

Venue
Pentahotel Leipzig
Grosser Brockhaus 3
04103 Leipzig (Germany)
Phone: +49 (0)341 12920

Date
Thursday, 01 & Friday, 02 March 2012

Fees
(before/after December 31, 2011)

270,00/ 320,00 €	members*
330,00/ 380,00 €	non-members
130,00/ 230,00 €	junior scientists
200,00 €	day ticket
25,00 €	Conference Dinner

*of AGAH, CPI, AHPPI, BAPU

AGAH e.V. http://www.agah.info/

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Online registration and hotel reservation by

http://www.intercom-kongresse.de/agah2012/

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AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

22nd Annual Meeting

The Role of the Patient in Human Pharmacology – A Changing Paradigm?

01 March & 02 March 2012, Leipzig (Germany)

4th Announcement

INTRODUCTION

There is a common assumption that toxic compounds to be developed, e.g., for oncologic indications must not be investigated in healthy subjects, and that is why, in those cases, the phase-I clinical programme is usually conducted in patients. But even beyond that, there has been an evolving discussion whether, or to what extent, suitable investigational compounds can be tested in patients during clinical phase I/IIa in order to streamline the clinical development programme and achieve proof-of-concept data at an early stage. This discussion is closely related to the role of special populations in early clinical development. Important topics in this context are dedicated studies in females, paediatric populations, elderlies and ethnical aspects. Further special aspects in this discussion are medical devices and drug/device-combinations. It is recognized that the identification of the most suitable population for clinical study is an important factor on the way to stratified medicine, but the discussion about the right target population is also influenced by safety considerations, the availability of appropriate biomarkers and translational approaches and, last but not least, regulatory aspects.

In Plenary Sessions and Parallel Workshops with much room for discussion, the AGAH Annual Conference 2012 will provide the floor for comprehensive exchange of experience and opinion on the future of the healthy subject in clinical trials – in times where rapid proof-of-concept is of utmost importance. Discussions about the most suitable populations for particular types of scientific questions and clinical trials as well as the specific challenges of study populations concerning age, gender and genetic disposition including optimised protection of these different kinds of study participants will be facilitated by this programme. Full sessions will be dedicated to population issues in oncology studies and the best way to get to rapid proof-of –concept.

WEDNESDAY, 29 FEBRUARY 2012

18:00	**Get Together**
19:00	**AGAH General Assembly**

THURSDAY, 01 MARCH 2012

08:00	Registration
09:00	Opening remarks *Ingrid Klingmann, Brussels*
Session 1	**Choosing the most appropriate study population in early-phase studies (healthy subjects or patients)**
Chairs	*Andreas Kovar, Georg Wensing*
09:10	Introduction to session topic by Chair
09:20	When are early-phase studies in patients mandatory? *Sebastian Harder, Frankfurt am Main*
09:50	When are early-phase studies more appropriate in patients as compared to healthy subjects? *Bernd Liedert, Darmstadt*
10:20	When are early-phase studies in patients not useful or even not acceptable? *Wolfgang Timmer, Mannheim*
10:50-11:20	**Break**
Session 2	**Consideration of gender in clinical trials**
Chairs	*Christine Klipping, Hildegard Sourgens*
11:20	Do gender-specific data from early phase clinical trials translate into therapeutic recommendations? *Kerstin Breithaupt-Grögler, Frankfurt am Main*
11:50	Practical aspects and feasibility of studies in females – aspects related to indication, hormonal status, pregnancy and lactation *Christine Klipping, Groningen* *Hildegard Sourgens, Munich*
12:30	Development of “life-style drugs” for men and women *Armin Schultz, Mannheim*
13:00-14:30	**Break**
14:30-16:00	**Parallel Workshops**
WS 1	Ethical issues in vulnerable populations *Gerhard Fortwengel, Hannover* *Ingrid Klingmann, Brussels*
WS 2	Dose selection for special populations (children, elderlies, renal & hepatic impairment) *Wolfgang Mück, Wuppertal* *Georg Wensing, Wuppertal*
WS 3	Studies with medical devices and drug/device-combinations in healthy subjects and patients including *in-vitro* technology studies (focus on therapeutic area respiratory diseases) *Sabine Häußermann, Gauting* *Dominik Kappeler, Gauting* *Sebastian Klammt, Rostock*
WS 4	When is a subject healthy? – Requirements by the German BfArM *Frank Donath, Erfurt* *Christoph Clemens Haufe, Erfurt* *Heidrun Reißenweber, Gräfelfing/Munich* *Hildegard Sourgens, Munich* *Thomas Sudhop, Bonn*
16:00-16:30	**Break**
Session 3	**Various ages: children – adolescents – elderlies**
Chairs	*Kerstin Breithaupt-Grögler, Barbara Schug*
16:30	Legal requirements to include children in clinical trials as patients, for diagnostic procedures and to prevent diseases *Antje Neubert, Erlangen*
17:00	IN/EX criteria in studies with healthy elderlies and special approaches with regard to geriatric patient populations (Pop-PK?) (Should we be using patients instead of healthy elderlies?) *Petra Thürmann, Wuppertal*
17:30	Open-forum discussion: "Similarities and differences in drug development for geriatric and pediatric populations"
18:00	End of Sessions Day 1
19:30	**Conference Dinner**