Annual Meeting 2004

Association for Applied Human Pharmacology
Arbeitsgemeinschaft für Angewandte Humanpharmakologie (AGAH e.V.)

SPECIAL POPULATIONS: WHAT MAKES THEM SO SPECIAL?

Current issues in study design, evaluation and regulatory affairs during drug development

Date: 29.02.-02.03.2004 Venue: Berlin, Schering AG

Conference Chairs:

- Christian Reh, Pharmacon, Berlin
- Barbara Schug, SocraTec R&D, Oberursel

Programme Committee:

- Kerstin Breithaupt-Grögler, Frankfurt
- Ulrike Ebert, Universität Heidelberg
- Charlotte Herrlinger, 4SC, Martinsried
- Carsten Meyerhoff, Health Management Consulting, Langenau
- Berno Müller, Pharmacon, Berlin
- Anne-Kathrin Riethling, Universität Rostock
- Bernd Rosenkranz, Jerini, Berlin
- Tomas Salmonson, Medicinal Products Agency, Uppsala
- Meinolf Wonnemann, SocraTec R&D, Oberursel
- Michael Zühlsdorf, Bayer, Wuppertal

Organisational Committee:

- Wolf Sittner, Schering, Berlin
- Amira Skapur, SocraTec R&D, Oberursel
- Yvonne Spiegel, Schering, Berlin
- Thomas Staks, Schering, Berlin
- Marianne Weiß, Schering, Berlin

Costs:

- 400 Euro after January 1, 2004
- 25 Euro reduction for AGAH-, ACCP-, and Club-Phase-I-Members
- 100 Euro participation on Sunday only
- 250 Euro for junior scientists below 30 years of age (limited numbers only)
- 150 Euro for junior poster presenters below 30 years of age

Annual Meeting 2004

Sunday, 29.02.2004: Workshops / Tutorials

10:00	- 13:30	12. AMG Novelle – aktueller Stand Phase-I-Studien im neuen regulatorischen Umfeld I. Klingmann, Pharmaplex, Brüssel; H. Fuder, Parexel, Berlin

10:00	Willkommen und Einleitung I. Klingmann, Brüssel
10:10	Europäische Hintergründe der Richtlinie 2001/20/EG B. Lehmann, European Commission, Brüssel
10:40	Die neue Verantwortung der Ethik-Kommissionen I. Wessler, LAEK Mainz, Wiesbaden
11:10	Antrag für das Genehmigungsverfahren F. Hackenberger, BfArM, Bonn
11:45	GCP-Inspektionen nach neuem Recht G. Schwarz, BfArM, Bonn
12:20	IMPD-Unterlagen zur pharmazeutischen Qualität für Phase-I-Studien im Vergleich zu späteren Prüfphasen S. Keitel, BfArM, Bonn
12:55	Adverse Events-Meldungen nach dem 1. Mai 2004 F. Hackenberger, BfArM, Bonn

11:00	- 13:30	Einführung in die Pharmakokinetik W. Cawello, Schwarz Pharma, Monheim

11:00	- 13:30	Earned Value Analysis (EVA) and Management (EVM) W. Seifert, Schering, Berlin

13:30	- 14:30	Study Nurse Meeting

14:30	- 15:30	Study Nurse Kurs Praktischer Umgang mit den Genehmigungsanträgen gemäß 12. AMG-Novelle und Rechtsverordnung bei Ethikkommissionen und BOB R. Frey, Bayer AG, Wuppertal

13:30 - 15:30 **Lunch Break**

Kaffeepausen werden während der Veranstaltungen bekannt gegeben

Sunday, 29.02.2004: Workshops / Tutorials

15:45 - 18:00	12. AMG Novelle – Diskussionsforum I. Klingmann, Pharmaplex, Brüssel; H. Fuder, Parexel, Berlin

15:45	Studienvorbereitung in der Phase I vor und nach dem 01. Mai 2004 Vorsitz: W. See, Focus, Neuss Teilnehmer: B. Lehmann, F. Hackenberger, I. Wessler, G. Schwarz, R. Frey, M. Seibert-Grafe • Informationszusammenführung beim Sponsor • Erstellung des IMPD • Konsistenz zwischen EUDRACT, IB, IMPD, Studienanträgen EK und BfArM • IT-Anforderungen
16:30	Studiendurchführung und Studienabschluss Vorsitz: D. Chase, Kendle, München Teilnehmer: F. Hackenberger, G. Mikus, R. Schulz, I. Klingmann, S. Keitel, H. Fuder • Amendments • Pharmakovigilanz • Meldung des Studienendes • Berichterstattung • Archivierung
17:15	Gewährleistung der Effektivität des neuen Systems durch optimale Kommunikation und Kollaboration aller beteiligten Parteien Vorsitz: I. Klingmann, Pharmaplex, Brüssel Teilnehmer: B. Lehmann, H. Fuder, W. Sittner, F. Hackenberger, I. Wessel, W. See, M. Seibert-Grafe, D. Chase, S. Keitel, G. Schwarz • Sponsor - CRO • Sponsor - Prüfer • Sponsor – Ethik-Kommission - Prüfer • Sponsor – BfArM – Ethik-Kommission

15:30 - 18:00	Grundlagen der Biometrie Beschreibende und schließende Statistik in klinischen Studien T. Sudhop, M. Reber, Abt. f. Klinische Pharmakologie, Universität Bonn

Kaffeepausen werden während der Veranstaltungen bekannt gegeben

18:00 - 19:00	**Delegates Come Together / Standing Dinner (Schering)**
19:00 - 21:30	**AGAH Members Meeting (Schering)**

Annual Meeting 2004

Monday, 01.03.2004

07:45		Opening of Congress Office
08:30	- 09:00	Welcome Thomas Gramatté, AGAH President, Wolf Sittner, Schering Representative Barbara Schug, Christian Reh, Conference Chairs
Session I		**The study population: points to consider for study planning** Chairs: Charlotte Herrlinger, Christian Reh
09:00	- 09:30	*Children:* rationale for definitions of subpopulations Matthias Schwab, Margarete-Fischer-Bosch Institute, Stuttgart
09:30	- 09:45	Discussion
09:45	- 10:15	*Ethnics:* relevance of the genotype with special focus on drug metabolising enzymes and transporters Ingolf Cascorbi, University of Greifswald
10:15	- 10:30	Discussion
10:15	- 10:45	**Coffee Break / Poster Presentation**
10:45	- 11:30	*Dialysed patients:* differences in dialysis methods – technical aspects Frantisek Lopot, University of Prague *Dialysed patients:* differences in dialysis methods – clinical relevance Sylvie Sulkova, University of Prague
11:30	- 11:45	Discussion
11:45	- 12:15	*Diabetics:* a patient group with special population characteristics Robert Hermann, Altana, Konstanz
12:15	- 12:30	Discussion
12:30	- 12:40	Presentation of invited session poster and discussion *Invited Session Poster:* Methods for determination of renal impairment – a critical review with special focus on Cockcroft-Gault Carsten Meyerhoff, Health Management Consulting, Langenau
12:40	- 14:00	**Lunch Break / Industry Exhibition**

Monday, 01.03.2004

Session II	**The study population: Clinical considerations** Chairs: Christine Klipping, Michael Zühlsdorf

14:00	-	14:30	Phenotypic and genetic heterogeneity in schizophrenia: pharmacogenetic studies Marcella Rietschel, Zentralinstitut für seelische Gesundheit, Mannheim
14:30	-	14:45	Discussion
14:45	-	15:15	Early drug development in obesity Hélène Alberini, Sanofi Synthelabo, Paris
15:15	-	15:30	Discussion
15:30	-	16:00	**Coffee Break / Poster Presentation**

Session III	**Design development in studies with special populations** Chairs: Ulrike Ebert, Berno Müller

16:00	-	16:30	Extrinsic factors and clinical trials in specific ethnic groups Annette Gross, GlaxoSmithKline, Sydney
16:30	-	16:45	Discussion
16:45	-	17:15	Reduction of inconveniences in studies with children – microtechniques in immunology Claudius U. Meyer, University of Mainz
17:15	-	17:30	Discussion
17:30	-	18:00	Clinical studies with cytostatics in children Alexandra Wagner-Bohn, University of Münster
18:00	-	18:15	Discussion
19:00			*Bus transfer to Reichstag*
19:30			**Conference Banquet (Reichstag)** Presentation of prizes (posters)

Tuesday, 02.03.2004

Session IV	**Study design and evaluation: Biometric planning and study evaluation** Chairs: Barbara Schug, Carsten Meyerhoff

08:30	-	09:00	Sample size and decision criteria: PK/PD modelling as basis for Δ definition or when are changes clinically relevant Willi Weber, Aventis, Frankfurt
09:00	-	09:15	Discussion
09:15	-	09:45	Influence of co-variates on study outcome in the elderly (age, weight, renal function and absorption) Bernd Rosenkranz, Jerini, Berlin
09:45	-	10:00	Discussion
10:00	-	10:30	**Coffee Break / Poster Session**
10:30	-	11:00	Inhibition of ovulation: The intelligent use of surrogate parameters Ingrid Duijkers, Dinox, Nijmegen
11:00	-	11:15	Discussion
11:15	-	11:45	Can well-designed phase II/III trials and populations PK evaluation be used as surrogate for studies in special populations and drug-drug interaction studies? Hans G. Schaefer, Boehringer Ingelheim, Biberach adR
11:45	-	12:00	Discussion

Session V	**The regulatory situation: Consequences for labelling and registration – a conclusion of the conference – Part A** Chairs: Tomas Salmonson, Bernd Rosenkranz

12:00	-	12:10	Presentation of invited session poster and discussion *Invited Session Poster:* Overview over study designs proposed in international guidelines Charlotte Herrlinger, Carsten Meyerhoff, Anne-Kathrin Riethling
12:10	-	12:40	Guidelines for the investigation of the effects of impaired hepatic function – a critical appraisal Christian de Mey, ACPS, Mainz
12:40	-	12:55	Discussion
13:00	-	14:30	**Lunch Break / Industry Exhibition**

Tuesday, 02.03.2004

Session V	**The regulatory situation: Consequences for labelling and registration – a conclusion of the conference – Part B** Chairs: Tomas Salmonson, Bernd Rosenkranz

14:30	-	14:50	Bridging studies for ethnics – a reduction in the number of studies for international approvals Beate Rohde, Wolf Sittner, Schering, Berlin, and Mitsuhiro Mori, Nihon-Schering, Osaka
14:50	-	15:00	Discussion
15:00	-	15:30	When are studies in special populations necessary? Tomas Salmonson, Medicinal Products Agency, Uppsala
15:30	-	15:45	Discussion
15:45	-	16:00	Session's summary of the conference chairs Christian Reh, Pharmacon, Berlin, Barbara Schug, SocraTec R&D, Oberursel
15:45	-	16:00	Closing Remarks Gerd Mikus, AGAH President