FACULTY Part I & II

Dr. Sybille Baumann
CRS Berlin GmbH, Berlin/Germany

Dr. Antje Blank
University Medical Center Heidelberg/Germany

Dr. Kerstin Breithaupt-Grögler
kbr - clinical pharmacolgy services, Frankfurt/Main/Germany

Dr. Martin Coenen
University Medical Center Bonn/Germany

Dr. Katharina Erb-Zohar
clinphase, Schotten/Germany

Christian Hinze
medcom drug development services GmbH, Rheinau/Germany

Dr. Andreas Kovar
Sanofi-Aventis Deutschland GmbH, Frankfurt/Main/Germany

Dr. Stephanie Plassmann
PreClinical Safety (PCS) Consultants Ltd, Basel/Switzerland

Die Inhalte der Fortbildungsmaßnahme sind produkt- und/oder dienstleistungsneutral gestaltet. Potenzielle Interessenkonflikte der Referierenden werden in einer Selbstauskunft gegenüber den Teilnehmenden offen gelegt werden. Der Introductory Course Part I + II ist eine Eigenveranstaltung der AGAH e. V. und wird nicht durch Sponsoring finanziert. Die Höhe der Gesamtaufwendungen beträgt ca. 25.000 € für die Ausrichtung.

FACULTY Part I & II

Dr. Jens Rengelhausen
Grünenthal GmbH, Aachen/Germany

Dr. Barbara Schug
SocraTec R&D GmbH, Oberursel/Germany

Prof. Dr. Hildegard Sourgens
Consultant, Munich/Germany

Dr. Jorg Taubel
Richmond Pharmacology Ltd, London/United Kingdom

Dr. Wolfgang Timmer
Inamed GmbH, Gauting/Germany

Dr. Manfred Wargenau
M.A.R.C.O. GmbH & Co. KG, Düsseldorf/Germany

Prof. Dr. Georg Wensing
Bayer Pharma AG, Wuppertal/Germany

Dr. Michael Zühlsdorf
Merck KGaA, Darmstadt/Germany

"Introductory Course in Exploratory Medicines Development" –
Part II · 31 March - 3 April 2020

INFORMATION

Venue
Haus der Begegnung
Bischof-Kaller-Straße 3
61462 Königstein im Taunus (Germany)

Date
Part I
29 January - 31 January 2020

Part II
31 March - 3 April 2020

Fees
Part I (3 days) **or** Part II (4 days)

1.100 EUR Member*
1.450 EUR Non Member

Part I **and** Part II

1.900 EUR Member*
2.500 EUR Non Member

*of AGAH, AHPPI, BAPU, AFPT-CPI, ACCP, EUFEMED

Special fees for students are available on request.

Minimum number of participants 10 guests
Registration deadline Part II: 16/3/2020

CONTACT AND FURTHER INFORMATION

AGAH e. V.
Association for Applied Human Pharmacology (AGAH) e. V.
Office: Goernestraße 30
20249 Hamburg
Phone: +49 (0)40 30772097
Email: info@agah.eu
http://www.agah.eu

Registration
CSi Hamburg GmbH
Goernestraße 30
20249 Hamburg (Germany)
Phone: +49 (0)40 30 770300
Fax: +49 (0)40 30 770301
Email: agah-meetings@csihamburg.de

Download_Registrationform (engl.) PDF

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

INTRODUCTORY COURSE
IN EXPLORATORY MEDICINES DEVELOPMENT

PART I

29 - 31 JANUARY 2020

Königstein im Taunus, Germany

INTRODUCTION AND LEARNING OUTCOMES

This course addresses postgraduates in life sciences interested in early clinical development of medicinal products. Two training parts of 3 days each provide a concise overview on Human Pharmacology / Translational Medicine spanning from non-clinical pharmacology and toxicology over first-in-man studies to pro-of-of-concept clinical trials.

Learning Outcomes

On successful completion of Part 1, students should be able to demonstrate an understanding / knowledge of the following:

- principal steps in drug development – from compound selection to marketing application and beyond
- pertinent issues involved in the undertaking of early clinical research
- specific aspects of how to set-up and conduct early phase clinical trials
- regulation of medicines in Europe
- development and review of compound-specific information to ensure adherence to scientific, medical, ethical, and legal provisions
- integration of pertinent available scientific information into an IB and a clinical trial protocol
- principles of trial design, protocol submission and clinical conduct
- selection of appropriate trial population
- most common early phase clinical trials and their specific requirements
- assessment and evaluation of safety data from clinical trials
- relevance of formulation properties and in vitro characteristics of the trial medication for design and planning of an early phase clinical trial
- basics of pharmacokinetics
- defining pharmacokinetic (PK) endpoints for early phase clinical trials
- method validation according to good clinical (GCP) and good laboratory (GLP) practise
- practical aspects of bioequivalence trials

This AGAH course meets the standards for high-quality postgraduate education and training in Medicines Development established by PharmaTrain and has been awarded a PharmaTrain Recognition. The course was accredited 3 ECTS (Parts I plus II).

programme modifications reserved

Day 1 · WEDNESDAY, 29 January 2020

09:00 - 09:30	Introduction of faculty and participants
09:30 - 10:30	**Overview on the drug development process:** Nonclinical studies, evaluation of toxicity, pharmacokinetics, pharmacodynamics First-in-human, Phases I to III, exploratory vs. confirmatory trials, submission and marketing authorisation; Phase IV, non-interventional studies / post-marketing surveillance, epi-demiological studies; go/no-go decision making, definition of proof-of-mechanism (PoM), proof-of-concept (PoC) *Georg Wensing*
10:30 - 10:45	Break
10:45 - 12:00	**Design elements of human pharmacology trials:** Controlled / uncontrolled, placebo / active control, cross-over / parallel-group, single-blind / double-blind, single dose / multiple dose, randomisation procedures, dose-escalation, staggered timing, combined protocols, adaptive elements, microdosing studies *Wolfgang Timmer*
12:00 - 12:45	**Regulatory and ethical aspects of trial conduct I:** Risk-benefit evaluation, GCP, Declaration of Helsinki, EU-Directive and Regulation, ICH-Guidelines *Kerstin Breithaupt-Grögler*
12:45 - 13:45	Break
13:45 - 14:30	**Regulatory and ethical aspects of trial conduct II:** Trial authorisation: Ethics committee favourable opinion and competent authority approval *Kerstin Breithaupt-Grögler*
14:30 - 15:00	Break
15:00 - 16:30	**Most common early phase clinical trials:** First-in-human, safety, exploratory PK and PD, drug-drug interaction, drug-food interaction, bioavailability, bioequivalence, QTc trials PoC trials *Wolfgang Timmer*
16:30 - 17:00	**First-in-human trials in patients:** Most common designs for dose escalation, relevant differences vs trials in healthy subjects *Antje Blank*
17:00 - 17:15	Break
17:15 - 18:00	**Trial protocol and investigator's brochure:** How to integrate information from scientific literature, nonclinical / clinical information and other sources; primary and secondary objectives vs. endpoints, differences between IB and IMPD *Kerstin Breithaupt-Grögler*
18:30 - 20:30	**Get together:** formation of break-out groups

Day 2 · THURSDAY, 30 January 2020

08:45 - 10:30	**Conduct of clinical trials** (including case study): Safety parameters and stopping criteria (AE, SAE, ADR, SUSAR), relationship to trial medication, severity of AE, liver / renal toxicity, general tolerability, local tolerance, monitoring of vital signs *Antje Blank*
10:30 - 10:45	Break
10:45 - 12:00	**Conduct of clinical trials:** (including case study)**:** Practical aspects in planning of early phase trials *Sybille Baumann*
12:00 - 13:00	Break
13:00 - 14:30	**Selection of trial population and definition of inclusion / exclusion criteria in early drug development** (including case study)**:** Healthy subjects, symptomatic subjects, patients in early phase, children, elderly, gender, ethnicities, cultural differences *Katharina Erb-Zohar* *Jorg Taubel*
14:30 - 15:00	**Conduct of clinical trials:** Site selection *Katharina Erb-Zohar*
15:00 - 15:15	Break
15:15 - 15:45	**Conduct of clinical trials:** (including case study)**:** Independant data monitoring committee *Katharina Erb-Zohar*
15:45 - 16:30	**Conduct of clinical trials:** Subject / patient i informed consent in early phase clinical trials *Kerstin Breithaupt-Grögler*
16:30 - 16:45	Break
16:45 - 17:00	**Quiz on essential terms:** Questions and answers provided by the audience *Kerstin Breithaupt-Grögler*
Evening	**Please prepare homework for Day 3**

Day 3 · FRIDAY, 31 January 2020

09:00 - 10:30	**Pharmacokinetics I:** ADME, drug-drug interaction, drug-food interaction, bio-equivalence / bioavailability, steady state, accumulation factors *Andreas Kovar*
10:30 - 10:45	Break
10:45 - 13:00	**Pharmacokinetics II:** Pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship *Andreas Kovar*
13:00 - 13:45	Break
13:45 - 14:00	**Discussion of homework:** Case studies: AE/SAE documentation, set-up of a FIH / a BE trial *Kerstin Breithaupt-Grögler*
14:00 - 16:00 *Break (flexible)*	**Trial medication:** Drug substance / product, labelling, stability, drug accountability, code breaking envelopes / emergency unblinding, specific aspects of preparation / adminis-tration / storage in Phase I, route of adminis-tration, formulations, fasted or fed conditions, blinding, double-dummy, test / reference therapy, challenging substances, IMPD in-formation, non-IMPD medication, release process according to ANNEX 1 *Kerstin Breithaupt-Grögler*
16:00 - 16:45	**Mandatory Test on Part I** 50% of questions must be correctly answered to pass test and receive a certificate
16:45 - 17:00	Feed back and end of Part I