FACULTY Part I & II

Dr Sybille Baumann
CRS Berlin GmbH, Berlin/Germany

PD 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

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

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

FACULTY Part I & II

Dr Jens Rengelshausen
Grünenthal GmbH, Aachen/Germany

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

Dr Jorg Taubel
Richmond Pharmacology Ltd, London/United Kingdom

Dr Wolfgang Timmer
Dr. Regenold GmbH, Badenweiler/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

Die Inhalte der Fortbildungsmaßnahme sind produkt- und/oder dienstleistungs-neutral 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. 20.000 € für die Ausrichtung.

"Introductory Course in Exploratory Medicines Development" –
Part II · 11 - 12 November and 15 -16 November 2021

INFORMATION

Venue
Online Course @
´Microsoft Teams`
-you will receive your personal login data-

Requirement
Please download the Desktop App
when you are asked

Date
Part I
30 September and 1 - 4 October 2021

Part II
11 - 12 and 15 - 16 November 2021

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

1.000 EUR Member*
1.350 EUR Non Member

Part I **and** Part II

1.750 EUR Member*
2.300 EUR Non Member

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

Special fees for students are available on request.

Min. number of participants 8 guests, Max. 20 guests
Registration deadline Part I: 23/9/2021

Registration (engl.)

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

AGAH
Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

INTRODUCTORY COURSE

IN EXPLORATORY MEDICINES DEVELOPMENT

PART I

-ONLINE COURSE-

30 SEPTEMBER - 4 OCTOBER 2021

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
COURSE RECOGNITION

EUFEMED

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 · THURSDAY, 30 September 2021

09:00 - 09:30	Meet and greet: 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 - 12:15	**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*
12:15 - 13:00	**Regulatory and ethical aspects of trial conduct I:** Risk-benefit evaluation, GCP, Declaration of Helsinki, EU-Directive and Regulation, ICH-Guidelines *Kerstin Breithaupt-Grögler*
13:00 - 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 - 17:15	**First-in-human trials in patients:** Most common designs for dose escalation, and relevant challenges treating patients in phase I *Antje Blank*
17:15 - 17:30	Break
17:30 - 18:15	**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*
18:15 - 18:45	**Virtual Get-together:** Apero and formation of break-out groups

Day 2 · FRIDAY, 1 October 2021

09:00 - 10:45	**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*
10:45 - 11:00	Break
11:00 - 12:30	**Conduct of clinical trials:** (including case study)**:** Practical aspects in planning of early phase trials *Sybille Baumann*
12:30 - 13:15	Break
13:15 - 14:45	**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*
14:45 - 15:15	**Conduct of clinical trials:** Site selection *Katharina Erb-Zohar*
15:15 - 15:30	Break
15:30 - 16:00	**Conduct of clinical trials:** (including case study)**:** Independant data monitoring committee *Katharina Erb-Zohar*
16:00 - 16:45	**Conduct of clinical trials:** Subject / patient i informed consent in early phase clinical trials *Kerstin Breithaupt-Grögler*

Weekend

Day 3 · MONDAY, 4 October 2021

09:00 - 09:15	**Discussion of homework:** Case studies: AE/SAE documentation, set-up of a FIH / a BE trial *Kerstin Breithaupt-Grögler*
09:15 - 11:00	**Pharmacokinetics I:** ADME, drug-drug interaction, drug-food interaction, bio-equivalence / bioavailability, steady state, accumulation factors *Andreas Kovar*
11:00 - 11:15	Break
11:15 - 13:30	**Pharmacokinetics II:** Pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship *Andreas Kovar*
13:30 - 14:15	Break
14:15 - 15:45	**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 *Barbara Schug*
15:45 - 16:00	Feed back and end of Part I
16:00 - 18:00 offline	**Mandatory Test on Part I** 60% of questions must be correctly answered to pass test and receive a certificate