

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 pharmacology 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

FACULTY Part I & II

Dr Jens Rengelhausen

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

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

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. 20.000 € für die Ausrichtung.

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

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 proof-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).

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, epidemiological studies; go/no-go decision making, definition of proof-of-mechanism (PoM), proof-of-concept (PoC) <i>Georg Wensing</i>
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 <i>Wolfgang Timmer</i>
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 <i>Kerstin Breithaupt-Grögler</i>
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 <i>Kerstin Breithaupt-Grögler</i>
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 <i>Wolfgang Timmer</i>

16:30 - 17:15	First-in-human trials in patients: Most common designs for dose escalation, relevant differences vs trials in healthy subjects <i>Antje Blank</i>
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 <i>Kerstin Breithaupt-Grögler</i>
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 <i>Antje Blank</i>
10:45 - 11:00	Break
11:00 - 12:30	Conduct of clinical trials: (including case study): Practical aspects in planning of early phase trials <i>Sybill Baumann</i>
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 <i>Katharina Erb-Zohar</i> <i>Jorg Taubel</i>
14:45 - 15:15	Conduct of clinical trials: Site selection <i>Katharina Erb-Zohar</i>
15:15 - 15:30	Break
15:30 - 16:00	Conduct of clinical trials: (including case study): Independant data monitoring committee <i>Katharina Erb-Zohar</i>

16:00 - 16:45	Conduct of clinical trials: Subject / patient informed consent in early phase clinical trials <i>Kerstin Breithaupt-Grögler</i>
---------------	---

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 <i>Kerstin Breithaupt-Grögler</i>
09:15 - 11:00	Pharmacokinetics I: ADME, drug-drug interaction, drug-food interaction, bio-equivalence / bioavailability, steady state, accumulation factors <i>Andreas Kovar</i>
11:00 - 11:15	Break
11:15 - 13:30	Pharmacokinetics II: Pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship <i>Andreas Kovar</i>
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 / administration / storage in Phase I, route of administration, formulations, fasted or fed conditions, blinding, double-dummy, test / reference therapy, challenging substances, IMPD information, non-IMPD medication, release process according to ANNEX 1 <i>Kerstin Breithaupt-Grögler</i>
15:45 - 16:00	Feed back and end of Part I
16:00 - 18:00	Mandatory Test on Part I 60% of questions must be correctly answered to pass test and receive a certificate
offline	