FACULTY Part I and II

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FACULTY Part I and II

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INFORMATION

Venue
Tagungshaus- und Bildungshaus
des Bistums Limburg
Wilhelm-Kempf-Haus 1
65207 Wiesbaden (Germany)

Date
Part I
12-14 June 2024

Part II
24-27 September 2024

Fees
Part I **or** Part II

1.000 EUR Member*
1.350 EUR Non Member

Part I **and** Part II

1.900 EUR Member*
2.300 EUR Non Member

*of AGAH, AHPPI, AFPT-CPI, Healixia, Polfemed

Special fees for students are available on request.

Min. number of participants 10 guests,
Registration deadline Part I: 15/05/2024

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AGAH
Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

INTRODUCTORY COURSE
IN EXPLORATORY MEDICINES DEVELOPMENT

PART I

12-14 JUNE 2024
face-to-face

Wiesbaden (Germany)

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 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 · WEDNESDAY | 12 JUNE, 2024

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, Basic principles of clinical drug development *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	**Conduct of clinical trials:** Subject / patient informed consent in early phase clinical trials *Kerstin Breithaupt-Grögler*
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*
19:00-21:00	**Get-together: Joint Dinner** and formation of break-out groups

Day 2 · THURSDAY | 13 JUNE 2024

09:00 - 10:45	**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 *Maria Anschütz / Annika Dax / Sarah Spriestersbach*
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
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	**What you always wanted to know** about clinical trials... *Diana Sims-Silbermann*
Homework	Case Studies

Day 3 · FRIDAY | 14 JUNE 2024

09:00 - 10:45	**Pharmacokinetics I:** ADME, drug-drug interaction, drug-food interaction, bioequivalence / bioavailability, steady state, accumulation factors *Andreas Kovar*
10:45 - 11:00	Break
11:00 - 13:15	**Pharmacokinetics II:** Pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship *Andreas Kovar*
13:15 - 14:00	Break
14:00 - 15:45	**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 / Diana Sims-Silbermann*
15:45 - 16:00	Break
16:00 - 16:45	**First-in-human trials in patients:** Most common designs for dose escalation, and relevant challenges treating patients in phase I *Martin Coenen / Diana Sims-Silbermann*
16:45 - 17:00	Feed back and end of Part I

MONDAY | 17 JUNE 2024

online	**Mandatory Test on Part I** 60 % of questions must be correctly answered to pass test and receive a certificate

Homework following Part I: Case study - Preparation of an early phase clinical trial at the site, to be handed in online