FACULTY Part I & II

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FACULTY Part I & II

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"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

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AGAH
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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

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, relevant differences vs trials in healthy subjects
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