

FACULTY PART I AND II

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INFORMATION

Date

Part I (online)
21 and 22 October 2026 (halfday)
28 and 29 October 2026 (halfday)
4 and 5 November 2026 (halfday)

Part II (Face 2 Face)
24–27 November 2026

Fees

Part I or Part II
1.700 EUR Member*
2.000 EUR Regular

Part I and Part II
2.800 EUR Member*
3.200 EUR Regular

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

Minimum number of participants 10 guests
Registration deadline:
20 September 2026

Special fees for students are available
on request.

If a company registers four participants,
the fifth place is free of charge.

“Introductory Course in Exploratory Medicines Development” –
**Part I · 21/22 October 2026 and 28/29 October 2026 and
4/5 November 2026.**

CONTACT AND FURTHER INFORMATION

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Registration

<https://forms.cloud.microsoft/e/NX4yPKmqP4>

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 angegebenen Uhrzeiten für Themenkomplexe sind Richtwerte. Anpassungen im Tagesverlauf erfolgen nach Bedarf. Die Höhe der Gesamtaufwendungen beträgt ca. 20.000 € für die Ausrichtung.



INTRODUCTORY COURSE IN EXPLORATORY MEDICINES DEVELOPMENT

PART II

**24–27 NOVEMBER 2026
face-to-face**

Oberursel (Germany)



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 I, 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).

A pre-reading list (e.g., ICH E8, E6, EU-CTR) will be provided upon course registration.

Day 1 · TUESDAY | 24 NOVEMBER 2026

09:00–09:45	What you always wanted to know about clinical trials... <i>Diana Sims-Silbermann</i>
09:45–10:15	Questions and Answers to online days
10:15–10:30	Break
10:30–13:00 15' break after 60'	Pharmacokinetics III: PK linearity / non-linearity / dose proportionality assessments, biopharmaceutics classification system (BCS), absorption half-life, flip-flop kinetics, protein binding, 4C-studies (mass-balance studies), allometric scaling <i>Andreas Kovar</i>
13:00–14:00	Break
14:00–18:30 30' break after 120'	Assessment of non-clinical data and risk as prerequisites before administration to man: Compound selection, early in vivo studies including primary and secondary pharmacodynamics and -kinetics, safety pharmacology, general toxicology in various species (rodents, non-rodents) including NOEL/NOAEL and MTD, safety ratio, toxicokinetics, genotoxicity, immunotoxicity, local tolerance, phototoxicity <i>Stephanie Plassmann</i>

Day 2 · WEDNESDAY | 25 NOVEMBER 2026

09:00–10:30	Assessment of non-clinical data and risk as prerequisites before administration to man (continuation of Day 1) <i>Stephanie Plassmann</i>
10:30–10:45	Break
10:45–11:15	The EMA guideline on early phase clinical trials – key elements <i>Kerstin Breithaupt-Grögler</i>
11:15–12:30	Case Study 1: How to determine a safe starting dose for first-in-human? Key safety parameters <i>Stephanie Plassmann</i>
12:30–13:30	Break

13:30–15:00	Case Study 1: How to determine a safe starting dose for first-in-human? Key safety parameters (continued) <i>Stephanie Plassmann</i>
15:00–15:15	Break
15:15–18:00 30' break	Case Study 2: Stop dose escalation or continue dosing? <i>Kerstin Breithaupt-Grögler</i> <i>Katharina Erb-Zohar</i>

Day 3 · THURSDAY | 26 NOVEMBER 2026

09:00–11:30 30' break	How to design an early clinical pharmacology development program? Basic concepts of early phase trials supporting early clinical development and decision making: how to design the first-in-human trial? how to proceed from single to multiple ascending dose? which questions needs to be answered prior to further clinical development?, including case study <i>Kerstin Breithaupt-Grögler</i> <i>Jens Rengelshausen</i>
11:30–11:45	Break
11:45–12:30	How to design an early clinical pharmacology development program? (continued) <i>Kerstin Breithaupt-Grögler</i> <i>Jens Rengelshausen</i>
12:30–13:30	Break
13:30–15:30 15' break	Pharmacodynamic endpoints and biomarker: Biomarkers for stratified medicine, companion diagnostics and proof of concept; biomarkers and PD endpoints in oncology, diabetes, cardiovascular diseases, cardiac safety and in pain <i>Jens Rengelshausen</i> <i>Michael Zühlsdorf</i>
15:30–15:45	Break
15:45–16:45	Data management: Principles (electronic) CRFs, queries, data cleaning, data base closure <i>Manfred Wargenau</i>

16:45–17:00	Break
17:00–17:45	Clinical trial report, lay summary of clinical trial results <i>Kerstin Breithaupt-Grögler</i>

Day 4 · FRIDAY | 27 NOVEMBER 2026

09:00–12:30	Analysis of early exploratory development studies - principles of medical statistics: Differences between treatments regarding biomarkers, pharmacokinetic / -dynamic effects, safety, parametric vs. non-parametric analysis, t-tests, repeated measures ANOVA, parametric vs. non-parametric analysis, Chi-square, Fisher's exact <i>Manfred Wargenau</i>
12:30–13:30	Break
13:30–15:15	Introduction to biologicals and biosimilars <i>Ruwen Böhm</i>
15:15–15:30	Feedback and Farewell

TUESDAY | 1 DECEMBER 2026

17:00–19:00	Mandatory Test conducted online (60 % of questions must be correctly answered to pass test and receive a certificate)
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