## FACULTY Part I & II

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## FACULTY Part I & II

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

## INFORMATION

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

**Date**
Part II
24-27 September 2024

**Fees**
Part II (4 days)

1.000 EUR Member*
1.350 EUR Non Member

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

Special fees for students are available on request.

Minimum number of participants 10 guests
Registration deadline Part II: 15/09/2024

## CONTACT AND FURTHER INFORMATION


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Register now https://forms.office.com/e/xZBqVHzMtr

AGAH
Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.
Association for Applied
Human Pharmacology

# INTRODUCTORY COURSE
# IN EXPLORATORY MEDICINES DEVELOPMENT

## PART II

**24 - 27 September 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 II, students should be able to demonstrate an understanding / knowledge of the following:

- nonclinical pharmacology and toxicology
- molecular basis of drug actions
- allometric scaling and dose proportionality assessments based on characteristic PK data
- defining pharmacodynamic (PD) endpoints and biomarkers
- differentiating between primary and secondary PK and PD endpoints
- How to design an early clinical pharmacology development plan
- planning and management of a first-in-man trial
- principles of data management and information flow
- principles of reporting and publication
- principles of medical statistics
- characteristic issues involved in the development of biologicals and biosimilars

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 · TUESDAY, 24 September 2024

| | |
|---|---|
| Homework | Pre-reading of case study for Wednesday (early clinical pharmacology development programme) |
| 09:00 - 09:15 | Introduction of faculty and participants |
| 09:15 - 11:15<br>5‘ break after 60‘ | **Pharmacokinetics III:**<br>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<br>*Andreas Kovar* |
| 11:15 - 11:30 | Break |
| 11:30 - 12:30 | **Bioequivalent trials:**<br>How to do it right - planning a successfull BE trial<br>*tba* |
| 12:30 - 13:30 | Break |
| 13:30 - 17:30<br>15‘ 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<br>*Stephanie Plassmann* |

## Day 2 · WEDNESDAY, 25 September 2024

| | |
|---|---|
| 09:00 - 10:30 | **Assessment of non-clinical data and risk as prerequisites before administration to man** (continuation of Day 1)<br>*Stephanie Plassmann* |
| 10:30 - 10:45 | Break |
| 10:45 - 11:15 | **The revised EMA guideline on early phase clinical trials – key elements**<br>*Kerstin Breithaupt-Grögler* |
| 11:15 - 12:30 | **How to determine a safe starting dose for first-in-human?** Key safety parameters, case study developed in break-out groups<br>*Stephanie Plassmann* |
| 12:30 - 13:15 | Break |
| 13:15 - 14:45 | **How to determine a safe starting dose for first-in-human?** Presentations of case study<br>*Stephanie Plassmann* |
| 14:45 - 15:00 | Break |
| 15:00 - 15:45 | **Stop dose escalation or continue dosing?**<br>Introduction to case study<br>*Katharina Erb-Zohar* |
| 15:45 - 16:45 | **Stop dose escalation or continue dosing?**<br>Case study developed in break-out groups |
| 16:45 - 17:30 | **Stop dose escalation or continue dosing?**<br>Presentation of case studies<br>*Katharina Erb-Zohar* |

## Day 3 · THURSDAY, 26 September 2024

| | |
|---|---|
| 09:00 - 10:00 | **Phase I trials in patients**<br>*Antje Blank, Martin Coenen* |
| 10:00 - 10:15 | Break |
| 10:15 - 12:30 | **How to design an early clinical pharmacology development program?**<br>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<br>*Jens Rengelshausen*<br>*Kerstin Breithaupt-Grögler* |
| 12:30 - 13:15 | Break |
| 13:15 - 14:00 | **How to design an early clinical pharmacology development program?** (continued)<br>*Kerstin Breithaupt-Grögler*<br>*Jens Rengelshausen* |
| 14:00 - 15:00 | **Molecular basis of drug action:**<br>Receptor pharmacology, agonists, antagonists, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug actions<br>*Martin Coenen* |
| 15:30 - 15:45 | Break |
| 15:45 - 17:30 | **Pharmacodynamic endpoints and biomarker:** Biomarkers for stratified medicine, companion diagnostics and proof of concept; biomarkers and PD endpoints in oncol logy, diabetes, cardiovascular diseases, cardiac safety and in pain<br>*Jens Rengelshausen*<br>*Michael Zühlsdorf* |

## Day 4 · FRIDAY 27 September 2024

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|---|---|
| 09:00 -10:00 | **Data management:**<br>Principles, electronic / paper CRFs, queries, data cleaning, data base closure<br>*Manfred Wargenau* |
| 10:00 - 10:15 | Break |
| 10:15 - 10:45 | **Clinical trial report** -<br>*Kerstin Breithaupt-Grögler* |
| 10:45 - 11:00 | Break |
| 11:00 - 12:45 | **Analysis of early exploratory development studies - principles of medical statistics:**<br>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<br>*Manfred Wargenau* |
| 12:45 - 13:30 | Break |
| 13:30 - 14:45 | **Analysis of early exploratory development studies - principles of medical statistics** (continued)<br>*Manfred Wargenau* |
| 14:45 - 15:00 | Break |
| 15:00 - 16:30 | **Introduction to biologicals and biosimilars** |
| 16:30 - 16:45 | **Feed back and end of Part II** |
| Monday,<br>30 September<br>17:00 - 19:00 | **Mandatory Test conducted online**<br>(60 % of questions must be correctly answered to pass test and receive a certificate) |