

FACULTY PART I AND II

Maria Anshütz
SocraTec R&D GmbH, Oberursel/Germany

Dr Sybille Baumann
CRS Berlin GmbH, Berlin/Germany

Prof. Dr Antje Blank
University Medical Center Heidelberg/Germany

Dr Ruwen Böhm
SocraTec R&D GmbH, Oberursel/Germany

Dr Kerstin Breithaupt-Grögler
kbr - clinical pharmacology services, Frankfurt/Germany

Dr Martin Coenen
University Medical Center Bonn/Germany

Annika Dax
SocraTec R&D GmbH, Oberursel/Germany

Dr Katharina Erb-Zohar
clinphase, Schotten/Germany

Dr Andreas Kovar
Sanofi-Aventis Deutschland GmbH, Frankfurt/Germany

Dr Stephanie Plassmann
PreClinical Safety (PCS) Consultants Ltd, Basel/
Switzerland

Dr Jens Rengelshausen
Uniklinik RWTH Aachen, Aachen/Germany

Dr Diana Sims-Silbermann
Trial Management Expert, Düsseldorf/Germany

Sarah Priestersbach
SocraTec R&D GmbH, Oberursel/Germany

Dr Jörg Täubel
Richmond Pharmacology Ltd, London/United Kingdom

Dr Wolfgang Timmer
Nuvisan GmbH, Gauting/Germany

Dr Manfred Wargenau
M.A.R.C.O. GmbH & Co. KG, Düsseldorf/Germany

Dr Ralph-Sтивен Wedemeyer
SocraTec R&D GmbH, Oberursel/Germany

Prof. Dr Georg Wensing
Senior Expert in Clinical Pharmacology,
Wuppertal/Germany

Dr Michael Zühlendorf
Senior Research Expert, Cologne/Germany

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 Part I:
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 II · 24–27 November 2026 (Face 2 Face).

CONTACT AND FURTHER INFORMATION

AGAH e. V. Association for Applied
Human Pharmacology (AGAH) e. V.
Office: Goernestraße 30
20249 Hamburg (Germany)

+49 (0)40 30772097
info@agah.eu
http://www.agah.eu

Conference Office CSi Hamburg GmbH
Goernestraße 30
20249 Hamburg (Germany)

+49 (0)40 30770 300
agah-meetings@csihamburg.de

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 I

21 and 22 OCTOBER 2026
28 and 29 OCTOBER 2026
4 and 5 NOVEMBER 2026
ONLINE



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 · WEDNESDAY | 21 OCTOBER 2026

13:00–14:00 **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)
Georg Wensing

14:00–14:15 Break

14:15–15:45 **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

15:45–16:00 Break

16:00–17:30 **Regulatory and ethical aspects of trial conduct I:** Risk-benefit evaluation, GCP, Declaration of Helsinki, Declaration of Taipei, EU-Regulation, ICH-Guidelines
Kerstin Breithaupt-Grögler

Day 2 · THURSDAY | 22 OCTOBER 2026

13:00–14:30 **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

14:30–14:45 Break

14:45–15:30 **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

15:30–15:45 Break

15:45–17:15 **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
Maria Anschutz / Annika Dax / Sarah Priestestersbach

Day 3 · WEDNESDAY | 28 OCTOBER 2026

13:00–14:30 **Conduct of clinical trials:** (including case study): Practical aspects in planning of early phase trials
Sybille Baumann

14:30–14:45 Break

14:45–15:30 **Conduct of clinical trials:** Participant Informed consent in early phase clinical trials
Kerstin Breithaupt-Grögler

15:30–15:45 Break

15:45–17:15 **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
Jörg Täubel

Day 4 · THURSDAY | 29 OCTOBER 2026

13:00–13:30 **Conduct of clinical trials:** Site selection
Katharina Erb-Zohar

13:00–14:00 **Conduct of clinical trials:** (including case study): Independent data monitoring committee
Katharina Erb-Zohar

14:00–14:15 Break

14:15–16:00 **Conduct of clinical trials** 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

16:00–16:15 **Homework:** Documentation of Case Studies: AE assessment
Antje Blank / Diana Sims-Silbermann

Day 5 · WEDNESDAY | 4 NOVEMBER 2026

13:00–13:30 Discussion of homework
Antje Blank / Diana Sims-Silbermann

13:30–14:15 **First-in-human trials in patients:** Most common designs for dose escalation, and relevant challenges treating patients in phase I
Antje Blank / Martin Coenen

14:15–14:30 Break

14:30–16:30 **Pharmacokinetics I:** ADME, drug-drug interaction, drug-food interaction, bioequivalence / bioavailability, steady state, accumulation factors
Andreas Kovar

16:30–16:45 Break

16:45–17:45 **Bioequivalence trials:** How to do it right - planning a successful BE trial
Ralph-Steven Wedemeyer

Day 6 · THURSDAY | 5 NOVEMBER 2026

13:00–15:30 **Pharmacokinetics II:** Pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship
Andreas Kovar

15:30–15:45 Break

15:45–16:45 **Molecular basis of drug action:** Receptor pharmacology, agonists, antagonists, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug actions
Martin Coenen

MONDAY | 9 NOVEMBER 2026

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