ORGANISATIONAL INFORMATION

Participation Fee

750 €	Regular
500 €	Member*
500 €	Junior Scientist up to the age of 30
250 €	Member of Regulatory Agencies or Ethics Committees

*of a EUFEMED society: AGAH, AHPPI, AFPT - Le Club Phase 1, HEALIXIA, POLFEMED

The participation fee is per person. Please note, according to §4 para 22 German turnover tax law, registration and workshop fees are exempt from VAT. Registration fees are charged and collected on behalf of AGAH e. V. All bookings are subject to change.

Registration Link

https://forms.cloud.microsoft/e/bsGeRS0gx3

Registration Deadline: 16 April 2026

VENUE

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Im Setzling 35
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Programme subject to modifications, status December 2025.

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The content of this event is designed to be product- and service-neutral. We confirm that the scientific management and the speakers will disclose potential conflicts of interest to the participants. General pharmacokinetic and toxicological principles are conveyed that do not relate to specific products or services. There is no sponsorship of the event, the total expenses of the event amount to approx. 8,000 € net and are financed by the participation fees and AGAH e. V.

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

AGAH WORKSHOP

TOXIC TRUTHS AND DOSING DILEMMAS

NAVIGATING EARLY DRUG DEVELOPMENT – TRANSLATIONAL ASPECTS OF CNS SAFETY FINDINGS

7–8 MAY 2026
OBERURSEL (GERMANY)

CONTENT

AGAH Workshop on the Early Safety Assessment of Drugs with a Focus on CNS Safety Findings – Concepts, Strategies, and Potential Pitfalls

Developing drugs with CNS-related safety concerns poses distinct challenges. Robust strategies are essential to identify, characterize, and mitigate risks early in clinical development. This AGAH workshop offers a deep dive into translational aspects, risk management strategies, and real-world lessons - including insights that shaped the 2018 revision of the EMA first-in-human guideline, designed to critically evaluate and refine decision-making in early-phase trials.

Key questions we will explore together:

1. Which early safety assessment results are most robust from a translational perspective?
2. What strategies best support human risk/benefit evaluation in drug development?
3. How have regulatory guidelines evolved to strengthen risk mitigation in first-in-human studies?

Real-world case studies – including both discontinued compounds (e.g., BIA 10-2474) and approved drugs – will illustrate these key questions. While the focus is on CNS-active compounds, the principles and strategies explored in this workshop are broadly applicable across therapeutic areas.

7 May 2026, 13:00–18:00

Day 1: Translational Challenges and Regulatory Framework

Session 1: Setting the Stage

13:00 **Welcome and introduction to workshop objectives**
- Participant expectations and interactive kick-off
- Overview of key challenges in CNS safety assessment

Session 2: Translational Robustness in Early Safety Data: Preclinical and Clinical Perspective

13:30 **Scientific input**: Interpreting preclinical CNS safety signals, insights into risk-benefit assessment for CNS-active compounds

14:30 **Scientific input**: Expectations from a clinical perspective, ethical considerations and communication with stakeholders

15:00 Break

Session 3: Case Study 1

15:30 **Introduction**

15:45 **Collaborative analysis** in groups

16:45 **Group discussion**
- Translational limitations and opportunities
- Strategies to support human risk/benefit evaluation

Session 4: Wrap-up of Day 1

17:45 –18:00 **Key takeaways** and **open questions** to be addressed on Day 2

19:00 Dinner and networking

8 May 2026, 08:30–13:00

Day 2: Strategies for Clinical Risk Assessment and Decision-Making

Session 5: Recap and Refocus

08:30 **Summary of Day 1** with **Q&A** and interactive warm-up

Session 6: Case Study 2

08:45 **Introduction**

09:00 **Collaborative analysis** in groups

10:05 **Group discussion**
- Translational limitations and opportunities
- Strategies to support human risk/benefit evaluation

11:15 Break

Session 7: Regulatory Expectations and Practical Approaches to Risk Mitigation in Early Trials

11:30 **Lessons learned** from past experience and how they shape current practice
- 2018 revision of the EMA guideline
- Practical implementation: Non-clinical and clinical aspects
- Lessons learned and impact on developmental strategies

Session 8: Round Table Discussion and Closing of Workshop

12:30 **Open discussion and wrap-up**

13:00 Farewell and lunch (optional)