



# AGAH

Arbeitsgemeinschaft  
für angewandte  
Humanpharmakologie e.V.

Association for Applied  
Human Pharmacology

## 29<sup>th</sup> ANNUAL MEETING

»TARGET-POPULATION DRIVEN DRUG DEVELOPMENT  
- CONTRIBUTION OF EARLY PHASES / CHALLENGES  
FOR EARLY PHASES / INPUT OF EARLY PHASES«

2<sup>nd</sup> and 3<sup>rd</sup> June 2022, Berlin | Germany

1<sup>st</sup> June 2022 | Pre-Meeting-Workshop

»Einführung der EU Verordnung über Klinische Prüfungen in der Praxis  
– Genehmigung einer monozentrischen humanpharmakologischen Prüfung  
im neuen regulatorischen Umfeld«

**-2G Regulation-**

fully vaccinated persons with valid proof of vaccination according to current RKI guidelines

Preliminary Program | status May 2022

Venue: Kaiserin-Friedrich Haus Berlin  
Robert-Koch-Platz 7  
10115 Berlin | Germany

### Pre-Meeting Workshop

Date: Wednesday, 1<sup>st</sup> June 2022  
Room: Seminarraum (2. Obergeschoss)  
Workshop language: German

### AGAH Annual Meeting

Date: Thursday, 2<sup>nd</sup> June and Friday, 3<sup>rd</sup> June 2022  
Room: Hörsaal  
Website: [www.agah.eu](http://www.agah.eu)  
Meeting language: English

Fees:	Early registration until 31/3/2022	Regular registration from 1/4/2022
<b>Pre-Meeting Workshop</b>		
Member <sup>1</sup>		220.- Euro
Regular/Guest		275.- Euro
Junior scientist <sup>2</sup>		140.- Euro
<b>Annual Meeting</b>		
Member <sup>1</sup>	370.- Euro	420.- Euro
Regular/Guest	450.- Euro	520.- Euro
Junior scientist <sup>2</sup>	260.- Euro	290.- Euro
<b>Combi Ticket</b>		
Member <sup>1</sup>	510.- Euro	580.- Euro
Regular/Guest	610.- Euro	710.- Euro
Junior scientist <sup>2</sup>	350.- Euro	390.- Euro
Conference Get-together	included	

<sup>1</sup>of AGAH e. V., AHPPI, AFPT-Le Club Phase I, HEALIXIA

<sup>2</sup>under age 30

## WELCOME

Dear colleagues

What concerns us most in drug development? Of course, in the end after a long journey through the clinical development process, a safe drug with excellent and outstanding efficacy for the benefit of patients is what we are striving for. And for us, paving the way in the early and translational phases of drug development we need to plan and execute everything in a safe, innovative and efficient manner.

Our scientific knowledge expands continuously and with that our tools to predict safety and efficacy accordingly. This conference aims to give an insight into modern, pharmacology-based strategies at translational stages of the development process. Are we able to learn meaningful results in healthy volunteers or should we start in patients already in phase 1? Which modern techniques and digital tools are being applied while striving to detect early efficacy and safety signals in patients during our clinical pharmacology studies? Learning and improved understanding of concentration-effect relationships help us in our ultimate goal to determine the right dose for the right patient. Applying the resulting principles does increase the predictive value and allows for extrapolation e.g., in pediatric patients.

Also, a scientific meeting these days would not be complete without addressing the recent key learnings for industry, academia, ethics committees, and regulatory bodies of conducting clinical studies during a pandemic.

More than 30 years after its birthday the AGAH annual meeting is intended to offer an inspiring atmosphere where attendees will be able to meet and to network with colleagues in Berlin safely.

Andreas Kovar  
President AGAH e. V.

Sybille Baumann  
President Elect AGAH e. V.

Georg Wensing  
Past President AGAH e. V.

### PROGRAM COMMITTEE

Sybille Baumann, Berlin  
Kerstin Breithaupt-Grögler, Frankfurt  
Rolf Burghaus, Wuppertal  
Christoph Coch, Munich  
Katharina Erb-Zohar, Schotten  
Frank Donath, Erfurt  
Joachim Höchel, Berlin  
Betsy Hughes-Formella, Reinbek  
Ingrid Klingmann, Brussels

Christine Klipping, Berlin  
Andreas Kovar, Frankfurt  
Gerd Mikus, Heidelberg  
Jens Rengelshausen, Aachen  
Barbara Schug, Oberursel  
Jörg Täubel, London  
Georg Wensing, Wuppertal  
Bettina Ziegele, Langen

## MITTWOCH, 1. JUNI 2022 (SEMINARRAUM)

### Pre-Meeting Workshop - in German language

»Einführung der EU Verordnung über Klinische Prüfungen in der Praxis  
– Genehmigung einer monozentrischen humanpharmakologischen Prüfung  
im neuen regulatorischen Umfeld«

Vorsitz Ingrid Klingmann, Brüssel; Claudia Riedel, Bonn

13:00–14:15 Das Antragsdossier Teil 1 und Teil 2 in Deutschland

Thorsten Ruppert, vfa, Berlin

Claudia Riedel, BfArM, Bonn

Gerd Mikus, Ethikkommission LÄK Stuttgart, Heidelberg

14:15–14:45 Pause

14:45–16:30 CTA Antrag und Genehmigungsprozess

inkl. wesentlicher Änderungen

Katharina Schacke, SocraTec, Oberursel

Sarah Heil, BfArM, Bonn

Guido Grass, AK Medizinischer Ethikkommissionen, Köln

16:30–17:00 Pause

17:00–18:00 Anwendung des neuen Verfahrens auf komplexe klinische

Prüfungen und integrierte Prüfpläne

Robert Schultz-Heienbrok,

CHARITÉ RESEARCH ORGANISATION GmbH, Berlin

Claudia Riedel, BfArM, Bonn

Gerd Mikus, Ethikkommission LÄK Stuttgart, Heidelberg

18:30 AGAH e. V. General Assembly/Mitgliederversammlung  
-Seminarraum-

## DAY 1 · THURSDAY, 2<sup>nd</sup> JUNE 2022 (ROOM HÖRSAAL)

08:45 Welcome and Introduction

Andreas Kovar, Frankfurt

09:00–09:45 Plenary lecture

Healthy subjects or patients in early phase non-oncology trials –  
mandatory, nice to have, or not indicated?

Claudia Riedel, Bonn

Session 1

Examples for 'clever' early phase trials in patients / healthy subjects

Gerd Mikus, Heidelberg; Jens Rengelshausen, Aachen

09:45–10:15

Challenges in Conducting a Covid-19 vaccine Trial- how to adjust to  
a continually changing pandemic Environment

Diana Sims-Silbermann, Neuss

10:15–10:45

From healthy volunteers to patients: In-vitro fertilisation  
as an example for development of a locally applied drug

Ingrid Duijkers, Groningen

10:45–11:15

From healthy volunteers to patients: Multi-stage pharmacodynamic  
drug-drug interaction investigations between vericiguat and nitrates

Michael Böttcher, Wuppertal

11:15–11:30 Break and Exhibition at Galerie (ground floor)

### BREAK-OUT SESSIONS

A  
Room Hörsaal

Challenges of target-population driven galenic development  
Christine Klipping, Berlin; Barbara Schug, Oberursel

11:30–12:15

Old and multimorbid – from patient involvement  
to better drug products

Sven Stegemann, Graz

12:15–13:00

Locally applied drugs: (a) intravaginally applied, locally acting

Barbara Schug, Oberursel

Locally applied drugs: (b) intravaginally applied, systemically acting

Klaus Nickisch, Berlin

## DAY 1 · THURSDAY, 2<sup>nd</sup> JUNE 2022 (ROOM HÖRSAAL)

**B** Innovative development in dermatological early phase trials  
Room Seminarraum **Betsy Hughes-Formella, Reinbek; Tessa van der Kolk, Leiden**

11:30–12:15 Time resolved in vivo PK/PD in skin:  
An essential tool for target-population driven drug development  
**Thomas Birngruber, Graz**

12:15–13:00 Proof of Pharmacology:  
Challenge models in dermatological early phase trials  
**Tessa van der Kolk, Leiden**

13:00–14:00 Break and Exhibition at Galerie (ground floor)

**Session 2** Emerging technologies in biomarker development /  
Imaging techniques  
**Kerstin Breithaupt-Grögler, Frankfurt; Jörg Täubel, London**

14:00–14:30 Dermatologic imaging vs scoring of skin -  
how objective is objective?  
**Wouter ten Voorde, Leiden**

14:30–15:00 Enriching functional MRI with molecular data: a novel perspective  
for pharmacological MRI studies  
**Ottavia Dipasquale, London**

15:00–15:30 Cardiovascular imaging in early medicines development  
**Amedeo Chiribiri, London**

15:30–16:00 Break and Exhibition at Galerie (ground floor)

## DAY 1 · THURSDAY, 2<sup>nd</sup> JUNE 2022 (ROOM HÖRSAAL)

**Session 3** Bridging Strategy in paediatric development  
**Ingrid Klingmann, Brussels; Andreas Kovar, Frankfurt**

16:00–16:25 Clinical and regulatory conditions for a bridging strategy  
**Christoph Male, Wien**

16:25–16:50 PK/PD requirements and tools enabling a bridging approach  
**Silke Gastine, Frankfurt**

16:50–17:15 Practical examples with bridging strategies  
**Corina Becker, Wuppertal**

17:15–17:30 Final discussion



17:30–20:00 Conference Get-together  
at Galerie (ground floor)





## Berlin

Kaiserin-Friedrich-Stiftung  
Robert-Koch-Platz 7  
10115 Berlin (Germany)