



AGAH

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

29th ANNUAL MEETING

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

2nd and 3rd June 2022, Berlin | Germany

1st June 2022 | Pre-Meeting-Workshop

»Practical implementation of the EU Clinical
Trial Regulation – how to start an early phase monocentre
trial under the new legislation?«

-2G Regulation-

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

Pre-Meeting Workshop

Date: Wednesday, 1st June 2022

Room: tba

Workshop language: German

AGAH Annual Meeting

Date: Thursday, 2nd June and Friday, 3rd June 2022

Room: Hörsaal

Website: www.agah.eu

Meeting language: English

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

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WEDNESDAY, 1st JUNE 2022 (ROOM »TBA«)

Pre-Meeting Workshop

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

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

14:15–14:45 Pause

14:45–16:30 CTA Antrag und Genehmigungsprozess
inkl. wesentlicher Änderungen
Maria Anschütz, SocraTec, Oberursel
tba
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

18:30 AGAH e. V. General Assembly Get-together

19:00 AGAH e. V. General Assembly/Mitgliederversammlung

DAY 1 · THURSDAY, 2nd 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?

Session 1

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

09:45–10:15 Immunological drug development in patients
Example: rheumatoid arthritis

10:15–10:45 From healthy volunteers to patients: In-vitro fertilisation
as an example for development of a locally applied drug

10:45–11:15 From healthy volunteers to patients: Multi-stage pharmacodynamic
drug-drug interaction investigations between vericiguat and nitrates

11:15–11:30 Break

BREAK-OUT SESSIONS

A
Room »tba« Challenges of target-population driven galenic development

11:30–12:15 Old and multimorbid – from patient involvement
to better drug products

12:15–13:00 Locally applied drugs: (a) intravaginally applied, locally acting
Locally applied drugs: (b) intravaginally applied, systemically acting

DAY 1 · THURSDAY, 2ND JUNE 2022 (ROOM HÖRSAAL)

B Room »tba«	Innovative development in dermatological early phase trials
11:30–12:15	Time resolved in vivo PK/PD in skin: An essential tool for target-population driven drug development
12:15–13:00	Proof of Pharmacology: Challenge models in dermatological early phase trials
13:00–14:00	Break
Session 2	Emerging technologies in biomarker development / Imaging techniques
14:00–14:30	Dermatologic imaging vs scoring of skin - how objective is objective?
14:30–15:00	CNS imaging and functional MRI in early phase clinical trials
15:00–15:30	Cardiovascular imaging in early medicines development
15:30–16:00	Break

DAY 1 · THURSDAY, 2nd JUNE 2022 (ROOM HÖRSAAL)

Session 3	Challenges in early paediatric development
16:00–16:20	Introductory lecture
16:20–16:40	Example 1
16:40–17:00	Example 2
17:00–17:20	Example 3
17:20–17:30	Final discussion
19:30	Conference Get-together

DAY 2 · FRIDAY, 3rd JUNE 2022 (ROOM HÖRSAAL)

Session 4 Lessons learned from clinical trials performed throughout the Covid-19 pandemic

09:00–09:15 Sponsors view

09:15–09:30 CRO view

09:30–09:45 Authority (PEI) view

09:45–10:00 Ethics committee view

10:00–10:30 Discussion

10:30–11:00 Break

Session 5 InSilico Approaches and Digital Markers

11:00–11:20 Digital patient data for real-world analysis and clinical trials

11:20–11:40 Patient stratification and identification of target population using AI

11:40–12:00 Virtual Elements in Clinical Trials

12:00–12:30 Digital Biomarkers and Monitoring Devices as Enabler in Drug Development

12:30–13:00 Digital aspects in (early) clinical trials – vision or reality, the perspective of the regulator

13:00 Concluding remarks

13:15 Farewell lunch snack