



AGAH

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

29th ANNUAL MEETING

**»TARGET-POPULATION
DRIVEN DRUG DEVELOPMENT -
CONTRIBUTION OF EARLY PHASES«**

23-24 April 2020
Cologne | Germany

Pre-Meeting-Workshop | 22 April 2020

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

Preliminary Program | status August 2019

Venue: Park Inn by Radisson Köln City West
Innere Kanalstraße 15
50823 Köln | Germany

Pre-Meeting-Workshop

Date: Wednesday, 22 April 2020

Room: tba

AGAH Annual Meeting

Date: Thursday, 23 April & Friday, 24 April 2020

Room: tba

Website: www.agah.eu

Meeting language: English

Fees:

	Early registration	Regular registration
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Pre-Meeting-Workshop

Member ¹	320.- Euro	370.- Euro
Regular/Guests	400.- Euro	470.- Euro
Junior scientist ²	170.- Euro	270.- Euro

Annual Meeting

Member ¹	320.- Euro	370.- Euro
Regular/Guests	400.- Euro	470.- Euro
Junior scientist ²	170.- Euro	270.- Euro

Day Ticket

270.- EUR

Networking Get-together

55.- EUR

¹of AGAH e. V., BAPU, AHPPI, AFPT-Le Club Phase I, EUFEMED

²under age 30

WEDNESDAY, 22 April 2020 (Room »tba«)

Pre-Meeting Workshop

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

13:00 – 14:15 CTA Dossier Part 1 and Part 2 in Germany
Sponsor representatives
Ethics committee representatives, Cologne
BfArM, Bonn (Germany)

14:15 – 14:45 Break

14:45 – 16:30 CTA application and approval process incl. substantial amendments
User representatives
BfArM, Bonn
Ethics committee representatives, Stuttgart

16:30 – 17:00 Break

17:00 – 18:00 Applying the new procedure to complex clinical trials
and integrated protocols
Sponsor representatives
BfArM, Bonn
Ethics committee representatives, Stuttgart

18:30 Get together

19:00 AGAH e. V. General Assembly

DAY 1 · THURSDAY, 23 April 2020 (Room »tba«)

08:45	Welcome and Introduction Georg Wensing, Wuppertal
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
10:15 – 10:45	Locally applied drug development (<i>In-vitro</i> fertilisation) - from healthy volunteer to patient
10:45 – 11:15	tba

11:15 – 11:30 Break

BREAK-OUT SESSIONS

A	Challenges of target-population driven galenic development
11:30 – 12:15	In geriatrics - technical options and trends
12:15 – 13:00	tba
B	Innovative development in dermatological early phase trials
11:30 – 12:15	Real-time PK/PD in the skin
12:15 – 13:00	Proof of Pharmacology: Challenge models in dermatological early phase trials

13:00 – 14:00 Break

DAY 1 · THURSDAY, 23 April 2020 (Room »tba«)

Session 2	Biomarkers predictive for the effects in target populations
14:00 - 14:30	In early phase dermatology trials
14:30 - 15:00	In early phase diabetic trials
15:00 - 15:30	Overview of use of biomarkers in early phase paediatric trials

15:30 - 16:00 Break

Session 3	Imaging techniques in early phase trials
16:00 – 16:30	CNS imaging, Functional MRI
16:30 – 17:00	Cardiovascular imaging
17:00 – 17:30	Dermatology
19:30	Networking Get-together

DAY 2 · FRIDAY, 24 April 2020 (Room »tba«)

Session 4 Challenges in paediatric bridging studies

09:00 – 09:30 The clinical trial management perspective

09:30 – 10:00 The investigator perspective

10:00 – 10:30 The bioanalytical perspective

10:30 – 11:00 Break

Session 5 Digital tools and markers

11:00 – 11:45 'Virtual trials' – *in vitro* data and healthy subject data used for simulation of patient trials

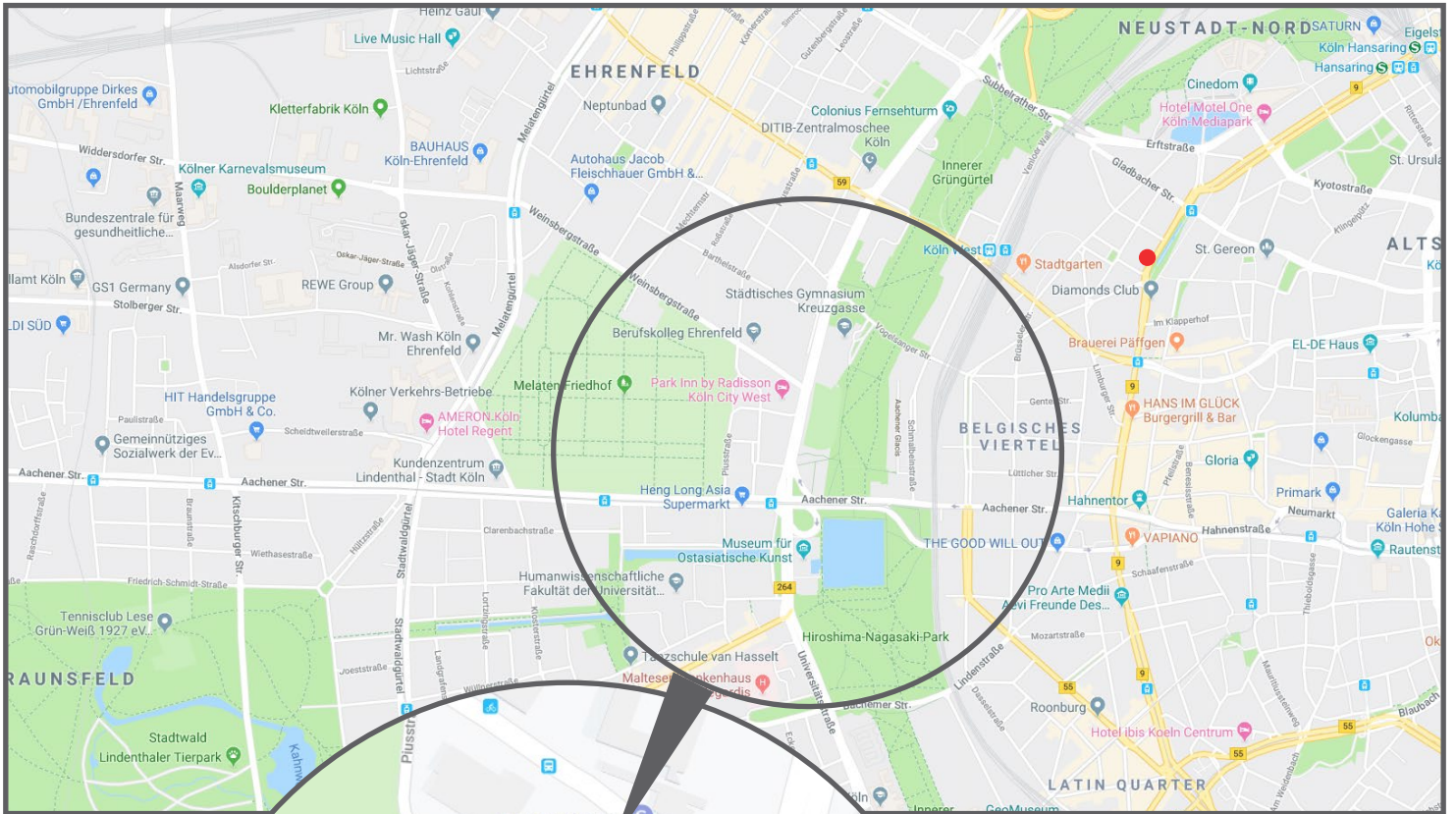
11:45 – 12:30 Biomarkers for cardiovascular pharmacodynamic effects - may 'digital' biomarkers provide more realistic data than bedside assessments?

12:30 – 13:30 Open-Forum Discussion on regulatory and development aspects of digital markers in today's data protection environment

13:30 Concluding remarks
Andreas Kovar, Frankfurt

13:45 Farewell lunch snack

subject to modifications, status July 2019



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Cologne

● Park Inn by Radisson Köln City West
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50823 Köln