



# 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«

23-24 April 2020  
Cologne | Germany

22 April 2020 | Pre-Meeting-Workshop

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

Preliminary Program | status February 2020

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

### Pre-Meeting Workshop

Date: Wednesday, 22 April 2020

Room: tba

Workshop language: German

### AGAH Annual Meeting

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

Room: Sydney-Tokio-Montreal

Website: [www.agah.eu](http://www.agah.eu)

Meeting language: English

Fees: 

	Early registration until 21/1/2020	Regular registration from 22/1/2020
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#### Pre-Meeting Workshop

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

#### Annual Meeting

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

#### Day Ticket

270.- EUR

#### Networking Get-together

55.- EUR

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

# WEDNESDAY, 22 April 2020 (Room »tba«)

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## Pre-Meeting Workshop

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

Ingrid Klingmann, Pharmaplex, Brüssel; Thomas Sudhop, BfArM, 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

Break

14:45 – 16:30

CTA Antrag und Genehmigungsprozess inkl. Wesentlicher Änderungen

Maria Anschütz, SocraTec, Oberursel

Thomas Sudhop, BfArM, Bonn

Guido Grass, AK Medizinischer Ethikkommissionen, Köln

16:30 – 17:00

Break

17:00 – 18:00

Anwendung des neuen Verfahrens auf komplexe klinische Prüfungen und integrierte Prüfpläne

Tobias Brand, Boehringer Ingelheim, Biberach

Sarah Heil & Ulrike Viehbahn, BfArM, Bonn

Gerd Mikus, Ethikkommission LÄK Stuttgart, Heidelberg

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18:30

Get-together

19:00

AGAH e. V. General Assembly

# DAY 1 · THURSDAY, 23 April 2020 (Room Sydney-Tokio-Montreal)

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- 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?  
Thomas Sudhop, Bonn

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**Session 1** Examples for 'clever' early phase trials in patients / healthy subjects  
Gerd Mikus, Heidelberg; Georg Wensing, Wuppertal

- 09:45 – 10:15 Immunological drug development in patients - Example: rheumatoid arthritis  
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  
Christine Klipping, Berlin
- 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

## BREAK-OUT SESSIONS

- A**  
Room »tba« Challenges of target-population driven galenic development  
Frank Donath, Erfurt; Christine Klipping, Berlin
- 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, 23 April 2020 (Room Sydney-Tokio-Montreal)

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<b>B</b> Room »tba«	Innovative development in dermatological early phase trials <b>Betsy Hughes-Formella, Reinbek; Robert Rissmann, Leiden</b>
11:30 – 12:15	Time resolved in vivo PK/PD in skin: An essential tool for target-population driven drug development <b>Frank Sinner, Graz</b>
12:15 – 13:00	Proof of Pharmacology: Challenge models in dermatological early phase trials <b>Robert Rissmann, Leiden</b>

13:00 – 14:00 Break

<b>Session 2</b>	Biomarkers predictive for the effects in target populations <b>Kerstin Breithaupt-Grögler, Frankfurt; Andreas Kovar, Frankfurt</b>
14:00 – 14:30	In early phase dermatology trials <b>Pieter Spee, Copenhagen</b>
14:30 – 15:00	In early phase diabetic trials - application of glucose clamp technique (e.g. for once weekly treatments in diabetes type I) <b>Tim Heise, Neuss</b>
15:00 – 15:30	Overview of use of biomarkers in early phase paediatric trials <b>Donato Bonifazi, Rom</b>

15:30 - 16:00 Break

<b>Session 3</b>	Challenges in paediatric bridging studies <b>Ingrid Klingmann, Brussels; Christoph Male, Vienna</b>
16:00 – 16:30	The clinical trial management perspective <b>Lucie Spatenková, Prague</b>
16:30 – 17:00	The investigator perspective <b>Christoph Male, Vienna</b>
17:00 – 17:30	The bioanalytical perspective <b>Björn Burkhardt, Dusseldorf</b>
19:30	Networking Get-together

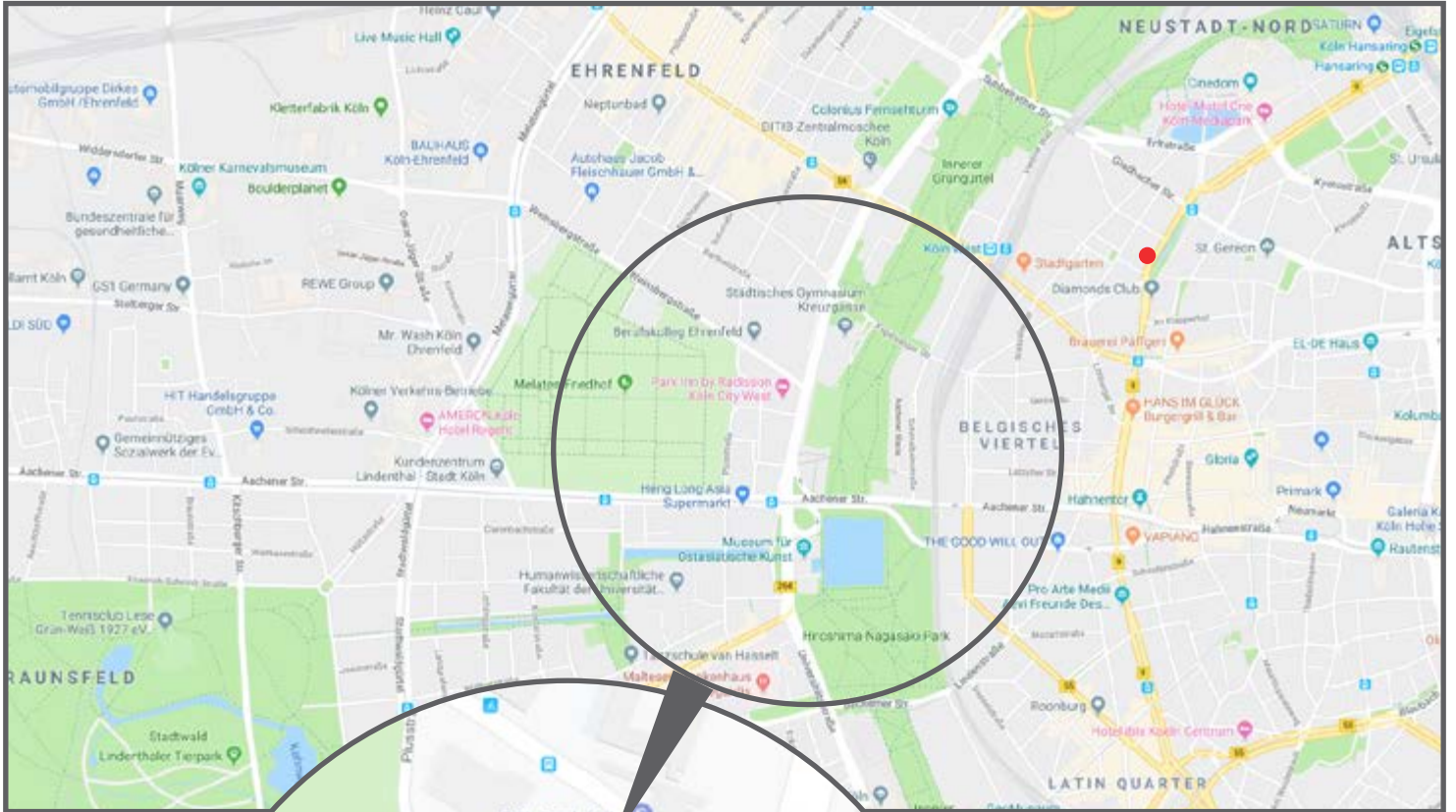
## DAY 2 · FRIDAY, 24 April 2020 (Sydney-Tokio-Montreal)

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Session 4	Imaging techniques in early phase trials Christoph Coch, Bergisch Gladbach; Jorg Taubel, London
09:00 – 09:30	CNS imaging and functional MRI in early phase clinical trials Ottavia Dipasquale, London
09:30 – 10:00	Cardiovascular imaging in early medicines development Amedeo Chiribiri, London
10:00 – 10:30	Dermatologic imaging vs scoring of skin - how objective is objective? Wouter ten Voorde, Leiden

10:30 – 11:00 Break

Session 5	Digital tools and markers Rolf Burghaus, Wuppertal; Jens Rengelshausen, Aachen
11:00 – 11:30	'Virtual trials' – in vitro data and healthy subject data used for simulation of patient trials Rolf Burghaus, Wuppertal
11:30 – 12:00	Biomarkers for cardiovascular pharmacodynamic effects - may 'digital' biomarkers provide more realistic data than bedside assessments? Frank Kramer, Wuppertal
12:00 – 13:00	Open-Forum Discussion on regulatory and development aspects of digital markers and medical apps in today's data protection environment  Introduction to open-forum discussion: use of medical apps in clinical trials - challenges of data capture and data protection Stephan Herrmann, Erfurt  Panel discussion members Rolf Burghaus, Wuppertal Stephan Herrmann, Erfurt Frank Kramer, Wuppertal Robert Rissman, Leiden tba
13:00	Concluding remarks Andreas Kovar, Frankfurt
13:15	Farewell lunch snack



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# Cologne

● Park Inn by Radisson Köln City West  
Innere Kanalstraße 15,  
50823 Köln