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

»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

Program subject to change, status May 2022

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

Pre-Meeting Workshop

Date: Wednesday, 1st June 2022

Room: Seminarraum (2. Obergeschoss)

Workshop language: German

AGAH Annual Meeting

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

Room: Hörsaal

Website: www.agah.eu

Meeting language: English

Fees:

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

[1]of AGAH e. V., AHPPI, AFPT-Le Club Phase I, HEALIXIA
[2]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, 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? 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, 2nd JUNE 2022 (ROOM HÖRSAAL)

B Room Seminarraum	Innovative development in dermatological early phase trials 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, 2nd 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)

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

Session 4	COVID as a trigger to rethink established processes Sybille Baumann, Berlin; Kerstin Breithaupt-Grögler, Frankfurt
09:00–09:05	Introduction Sybille Baumann, Berlin
09:05–09:15	Sponsor Joachim Höchel, Berlin
09:15–09:25	Contract research organization Barbara Schug, Oberursel
09:25–09:35	Competent authority (PEI) Bettina Ziegele, Langen
09:35–09:45	Ethics committee Gerd Mikus, Heidelberg
09:45–10:30	Joint discussion and summary
10:30–11:00	Break and Exhibition at Galerie (ground floor)
Session 5	In-silico approaches and digital markers Rolf Burghaus, Wuppertal; Christoph Coch, Munich
11:00–11:30	Digital patient data and biomarkers as enabler in drug development and clinical research Christoph Coch, Munich; Frank Kramer, Wuppertal
11:30–11:50	Patient stratification and identification of target population using AI Holger Fröhlich, Sankt Augustin
11:50–12:10	Virtual elements in clinical trials Rolf Burghaus, Wuppertal
12:10–12:30	Digital aspects in (early) clinical trials – vision or reality, the perspective of a regulator Lukas Aguirre Davila, Langen
12:30-12:45	Discussion
12:45	Concluding remarks Sybille Baumann, Berlin
13:00	Farewell lunch snack

NOTES

SPEAKERS & CHAIRS IN ALPHABETICAL ORDER

Aguirre Dávila, Lukas Dr, Paul-Ehrlich-Institut, Langen/Germany

Baumann Sybille, Dr, CRS Clinical Research Services Berlin GmbH, Berlin/Germany

Becker Corina, Dr, Bayer Pharma AG, Wuppertal/Germany

Birngruber Thomas, Dr, Joanneum Research, Graz/Austria

Böttcher Michael, Bayer Pharma AG, Wuppertal/Germany

Breithaupt-Grögler Kerstin, Dr, -kbr- clinical pharmacology services, Frankfurt/Germany

Burghaus Rolf, Dr, Bayer Pharma AG, Wuppertal/Germany

Chiribiri Amedeo, Dr, King's College London, London/United Kingdom

Coch Christoph, Dr, nextevidence, München/Germany

Dipasquale Ottavia, PhD, King's College London, London/United Kingdom

Duijkers Ingrid, Dr, dinox, Groningen/The Netherlands

Fröhlich Holger, Prof Dr, Fraunhofer SCAI, Sankt Augustin/Germany

Gastine Silke, Sanofi Deutschland GmbH, Frankfurt/Germany

Grass Guido, Dr, AK Medizinischer Ethikkommissionen, Köln/Germany

Heil Sarah, Dr, BfArM Bundesinstitut für Arzneimittel und Medizinprodukte, Bonn/Germany

Höchel Joachim, Bayer Pharma AG, Berlin/Germany

Hughes-Formella Betsy, Dr, DermConsult, Reinbek/Germany

Klingmann Ingrid, Dr, Pharmaplex bvba, Brussels/Belgium

SPEAKERS & CHAIRS

Klipping Christine, Dr, dinox, Berlin/Germany

Kovar Andreas, Dr, Sanofi Deutschland GmbH, Frankfurt/Germany

Kramer Frank, Dr, Bayer Pharma AG, Wuppertal/Germany

Male Christoph, Ao. Univ.-Prof. Dr, Universitätsklinik für Kinder- und Jugendheilkunde, AKH Wien/Austria

Mikus Gerd, Prof Dr med, Ethikkommission LÄK Stuttgart, Heidelberg/Germany

Nickisch Klaus, Prof Dr, Evestra GmbH, Berlin/Germany

Niemeyer-van der Kolk Tessa, Dr, Universiteit Leiden, Leiden/The Netherlands

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Schultz-Heienbrok Robert, Charité Research Organisation GmbH, Berlin/Germany

Sims-Silbermann Diana, Dr, Janssen-Cilag GmbH, Neuss/Germany

Stegemann Sven, Prof Dr, Lonza Pharma & Biotech, Graz/Austria

Täubel Jörg, Dr, Richmond Pharmacology Ltd., London/United Kingdom

ten Voorde Wouter, Universiteit Leiden, Leiden/The Netherlands

Ziegele Bettina, Paul-Ehrlich-Insitut, Langen/Germany

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Beitrittserklärung/Application for Membership

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