



AGAH CONFERENCE 2026

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology



FRANKFURT

**»OPTIMISM, COURAGE, AND PRAGMATISM
– HUMAN PHARMACOLOGY 2030«**

25 and 26 February 2026, Frankfurt | Germany

24 February 2026 | Pre-Meeting-Workshop

»Physiology-Based Pharmacokinetic (PBPK) model application
in Model-Informed Drug Development (MIDD)«

status February 2026 - subject to change without notice

Venue: Haus am Dom
Domplatz 3
60311 Frankfurt am Main

Pre-Meeting Workshop »Physiology-Based Pharmacokinetic (PBPK) model application in Model-Informed Drug Development (MIDD)«

Date: Tuesday, 24 February 2026

Room: „Giebelsaal“

Workshop language: English

AGAH Conference »Optimism, Courage, and Pragmatism – Human Pharmacology 2030«

Date: Wednesday, 25 February and Thursday, 26 February 2026

Room: „Großer Saal“

Website: www.agah.eu

Meeting language: English

Fees: **Early registration** **Regular registration**
Until 31 October 2025 From 1 November 2025

Pre-Meeting Workshop (only)

Member ¹	250.- Euro	300.- Euro
Regular/Guest	350.- Euro	400.- Euro
Junior scientist ²	200.- Euro	--

Annual Conference (only)

Member ^{1, 3, 4}	450.- Euro	600.- Euro
Regular ³	650.- Euro	800.- Euro
Junior scientist ^{2, 3}	300.- Euro	--

Combi Ticket

Member ^{1, 3, 4}	600.- Euro	750.- Euro
Regular ³	800.- Euro	950.- Euro
Junior scientist ^{2, 3}	400.- Euro	--
Conference Get-together	included	included

¹of AGAH e. V., ACRON, AHPPI, AFPT-Le Club Phase I, HEALIXIA, POLFEMED

²under age 30, reduced price only available at early-bird registration

³reduction of early registration fee by 100 €, if you submit a poster abstract and present a poster at the AGAH Conference

⁴reduction of early registration fee by 100 €, if you are retired (AGAH members only), no combination with other reductions

WELCOME

Dear colleagues

Emerging tools, like artificial intelligence and advanced model-informed drug development (MIDD), disrupt our industry. Early clinical development and clinical pharmacology in particular need to get ready for keeping pace and driving new paradigms in early medicines development. The AGAH Conference 2026 will focus on these cutting-edge game changers with sessions on:

- Model-Informed Drug Development – Progress and Outlook
- Dose Selection for Phase 2 and Phase 3 – Optimal and Optimus
- Overly Complex Early Phase Trials – Proposals for Improvement
- Artificial Intelligence Impacting Clinical Pharmacology – A Dynamic Field of Opportunities
- Regulatory Enablers of Innovative Early Medicines Development

We are looking forward to welcome you to the AGAH Conference 2026 in Frankfurt.

Joachim Höchel
President AGAH e. V.

Jörg Täubel
President Elect AGAH e. V.

Sybille Baumann
Past President AGAH e. V.

PROGRAMME COMMITTEE

Sybille Baumann
Rolf Burghaus
Klaus Francke
Joachim Höchel
Burkhard Kerlin
Ingrid Klingmann

Andreas Kovar
Gerd Mikus
Jörg Täubel
Robert Schultz-Heienbrok
Michael Zühlsdorf

TUESDAY, 24 FEBRUARY 2026

Pre-Meeting Workshop
Room „Giebelsaal“

»Physiologically Based Pharmacokinetic (PBPK) model application in Model-Informed Drug Development (MIDD)«

Chairs

Rolf Burghaus - Bayer AG
Stephan Schaller - ESQlabs GmbH

13:00–13:15 Welcome and introduction into the workshop

13:15–14:00 PBPK - Whats that?
Annika Schneider - Bayer AG

14:00–14:30 Break

14:30–15:00 PBPK and Special Populations
Ibrahim Ince - Boehringer Ingelheim Pharma GmbH & Co. KG

15:00–15:30 Physiologically-Based Biopharmaceutics Modeling
Erik Sjögren - Pharmetheus AB

15:30–16:00 PBPK and Drug-Drug Interactions
Jan Schlender - Novartis

16:00–16:30 Break

16:30–17:30 Open Systems Pharmacology:
Science Community and Qualified Software Suite
Stephan Schaller - ESQlabs GmbH

18:00 Get-together (AGAH Member)

18:30 AGAH e. V. General Assembly/Mitgliederversammlung
Room „Seminarraum“

DAY 1 · WEDNESDAY, 25 FEBRUARY 2026

Room „Großer Saal“

09:00 Welcome and Introduction

Joachim Höchel - President AGAH e. V.

09:15–09:45 Keynote Presentation

The Value Continuum of PKPD:
From Post-Marketing to Preclinical Development
Bernd Meibohm - University of Tennessee

09:45–10:00 Discussion

10:00–10:30 Networking, Poster Viewing and Meet the Exhibitors

Session 1 **Model-Informed Drug Development – Progress and Outlook**

Chairs

Joachim Höchel - Bayer AG
Andreas Kovar - Sanofi

10:30–11:00 Implementing the ICH M15
Model-Informed Drug Development Paradigm
Jörg Lippert - Bayer AG

11:00–11:15 Discussion

11:15–11:30 Question-driven Practice of Disease Progression Modeling
and other MIDD Approaches:
Case-studies in Immunology and Oncology
Sathej Gopalakrishnan - Merck KGaA

11:30–11:45 Applying MIDD in Practice:
Extrapolating Upadacitinib Efficacy in Juvenile Idiopathic Arthritis
Using PK, Exposure-Response Models, and Real-World Data
Sven Mensing - AbbVie Deutschland GmbH & Co KG

11:45 - 12:00 From Efficient Lead Selection to Mechanistic Translation
Henrik Cordes - Sanofi

12:00–12:30 Joint discussion of all presentations of Session 1

12:30–13:30 Networking, Poster Viewing and Meet the Exhibitors

DAY 1 · WEDNESDAY, 25 FEBRUARY 2026

Session 2 Chairs	Dose Selection for Phase II and Phase III - Optimal and Optimus Gerd Mikus - Freie Universität Berlin Michael Zühlsdorf - Translational Science Consulting
13:30–14:00	Project Optimus and Dose Finding for Phase II and III in Oncology Sven Wind - Boehringer Ingelheim Pharma GmbH & Co. KG
14:00–14:30	Dose Finding for Small Molecules: Tyrosine Kinase Inhibitor Michael Zühlsdorf - Translational Science Consulting
14:30–15:00	Dose Finding for Monoclonals Bernd Meibohm - University of Tennessee
15:00–15:30	Discussion
15:30–16:00	Networking, Poster Viewing and Meet the Exhibitors
Session 3 Chairs	Overly Complicated Early Phase Live on stage: Stakeholder Interviews about Challenges and Solutions Sybille Baumann - CRS Clinical Research Services Berlin GmbH Klaus Francke - Bayer AG
16:00–16:10	Introduction Klaus Francke - Bayer AG
16:10–16:25	Sponsor Perspective Fabian Müller - Boehringer Ingelheim Pharma GmbH & Co. KG
16:25–16:40	Investigator Perspective Jelle Klein - SGS Belgium NV
16:40–16:55	Regulatory Authority Perspective Claudia Riedel - Bundesinstitut für Arzneimittel und Medizinprodukte
16:55–17:10	Ethics Committee Perspective Gerd Mikus - Freie Universität Berlin
17:10–17:25	Participant Perspective Manuel Welte - Germany
17:25–17:50	Audience Discussion with Panelists
17:50–18:00	Conclusion and Summary of the Discussion Sybille Baumann - CRS Clinical Research Services Berlin GmbH
18:00–20:30	Conference Get-together

AGAH Breakfast Session - Meet the Expert

Fruity snacks and valuable insights – breakfast conversations to foster mutual exchange with colleagues in their career development

Chairs Sybille Baumann - CRS Clinical Research Services Berlin GmbH
 Klaus Francke - Bayer AG
 Ingrid Klingmann - Pharmaplex bv
 Gerd Mikus - Freie Universität Berlin

07:45–08:45 This very informal session is intended for young scientists who would like to get in contact with experts who have worked for several years in different areas of early clinical development, in CROs, in consulting, in industry, in regulatory, in academia...

They are at your disposal for any questions on career pathways in early clinical development, crucial skills, training recommendations – and what else you always wanted to know.

Small breakfast will be served.

DAY 2 · THURSDAY, 26 FEBRUARY 2026

Session 4

Poster Slam - not in rhymes

Poster Pitches of Selected Abstracts

- Audience Voting* for Best Poster Award

Moderators

Joachim Höchel - President AGAH e. V.

Gerd Mikus - Freie Universität Berlin

09:00–09:45

Based on the abstracts submitted and accepted

3-min oral presentations, followed by 2 minutes for discussion.

09:00–09:05

Early Safety Signal Detection Using Semantic Medical Terminology Mapping

Francois Vandenhende - ClinBAY

09:05–09:10

Evolution in early phase clinical trial complexity over the last 10 years: a single site review

Tom Deschuytere - SGS Clinical Pharmacology Unit

09:10–09:15

Optimization of step-up dosing regimen of T-cell engagers to mitigate cytokine release syndrome using quantitative systems pharmacology modeling: tarlatamab case study

Oleg Demin Jr - InSysBio CY

09:15–09:20

“Powerful” drug-drug interaction studies; simple but efficient design

Aernout van Haarst - Celerion

09:20–09:25

Potential use of AI as a new frontier for safety follow-up in early phase clinical research: a thought experiment

Thomas De Ridder - SGS Clinical Pharmacology Unit

09:25–09:30

CTIS - The first 10,000 Submissions

Ulrike Behr - Charité Research Organisation

09:30–09:35

A comparison of Accelerated drug development pathways - EU, UK and USA

Lisa Campbell - Richmond Pharmacology

*Voting takes place via Mentimeter.

DAY 2 · THURSDAY, 26 FEBRUARY 2026

Session 5

Artificial Intelligence Impacting Clinical Pharmacology – A Dynamic Field of Opportunities

Chairs

Burkhard Kerlin - Bayer AG

Michael Zühlsdorf - Translational Science Consulting

09:45–10:05

Bridging the Black Box: Leveraging AI and Quantitative Systems
Pharmacology (QSP) to De-Risk Clinical Development

Cristhyne Leon - Nova In Silico

10:05–10:10

Discussion

10:10–10:30

Digital Protocol Development

Burkhard Kerlin - Bayer AG

10:30–10:35

Discussion

10:35–10:55

AI in Clinical Trials: Balancing Innovation with Regulatory Compliance

Torsten Stemmler - Bundesinstitut für Arzneimittel und Medizinprodukte

10:55–11:00

Discussion

11:00–11:30

Panel Discussion

11:30–12:00

Networking, Poster Viewing and Meet the Exhibitors

Session 6

Regulatory Enablers of Innovative Early Medicines Development

Chairs

Ingrid Klingmann - Pharmaplex bv

Robert Schultz-Heienbrok - Charité Research Organisation GmbH

12:00–12:30

Predictive Biomarkers in Drug Development -- Co-Developing
Diagnostics-Medicines Tandems:

Regulatory-Scientific Challenges and Current Initiatives

Silvia Vogl - Paul-Ehrlich-Institut

12:30–12:40

Discussion

12:40–13:10

The Promise of GCP R3 Guideline:

Risk Proportionality in Action – an Inspector's View

Torsten Stemmler - Bundesinstitut für Arzneimittel und Medizinprodukte

13:10–13:20

Discussion

13:20–13:50

The Promise of the German Medical Research Act:

A Specialised Ethics Committee for First-in-Human Studies
– Faster, Higher, Stronger?

Ulrike Artmeier-Brandt - Spezialisierte Ethik-Kommission
für besondere Verfahren

13:50–14:00

Discussion

14:00–14:15

Concluding Remarks and Best Poster Prize

Jörg Täubel - President Elect AGAH e. V.

14:15–15:00

Farewell Lunch Snack

SPEAKERS AND CHAIRS

Artmeier-Brandt, Ulrike, Dr • Spezialisierte Ethik-Kommission für besondere Verfahren • Bonn, Germany

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

Burghaus, Rolf, Dr • Bayer AG • Wuppertal, Germany

Cordes, Henrik, Dr • Sanofi • Frankfurt am Main, Germany

Francke, Klaus, Dr • Bayer AG • Berlin, Germany

Gopalakrishnan, Sathej, Dr • Merck KGaA • Darmstadt, Germany

Höchel, Joachim, Dr • Bayer AG • Berlin, Germany

Ince, Ibrahim, Dr • Boehringer Ingelheim Pharma GmbH & Co. KG • Ingelheim am Rhein, Germany

Kerlin, Burkhard • Bayer AG • Wuppertal, Germany

Klein, Jelle, Dr • SGS Belgium NV • Antwerpen, Belgium

Klingmann, Ingrid, Dr • Pharmaplex bv • Wezembeek-Oppem, Belgium

Kovar, Andreas, Dr • Sanofi • Frankfurt am Main, Germany

Leon, Cristhyne Dr • Nova In Silicio • Lyon, France

Lippert, Jörg, Dr • Bayer AG • Leverkusen, Germany

Meibohm, Bernd, Prof. Dr • University of Tennessee • Memphis, United States

Mensing, Sven, Dr • AbbVie Deutschland GmbH & Co KG • Ludwigshafen am Rhein, Germany

Mikus, Gerd, Prof. Dr • Freie Universität Berlin • Berlin, Germany

Müller, Fabian, Dr • Boehringer Ingelheim Pharma GmbH & Co. KG • Biberach an der Riß, Germany

Riedel, Claudia, Dr • Bundesinstitut für Arzneimittel und Medizinprodukte • Bonn, Germany

Schaller, Stephan, Dr • ESQlabs GmbH • Saterland, Germany

Schlender, Jan, Dr • Novartis • Basel, Switzerland

Schneider, Annika, Dr • Bayer AG • Leverkusen, Germany

Schultz-Heienbrok, Robert, Dr • Charité Research Organisation GmbH • Berlin, Germany

Sjögren, Erik, Prof. Dr • Pharmetheus AB • Uppsala, Sweden

Stemmler, Torsten, Dr • Bundesinstitut für Arzneimittel und Medizinprodukte • Köln, Germany

Täubel, Jörg, Dr • Richmond Pharmacology • London , United Kingdom

Vogl, Silvia, Dr • Paul-Ehrlich-Institut • Langen, Germany

Wind, Sven, Dr • Boehringer Ingelheim Pharma GmbH & Co. KG • Ingelheim am Rhein, Germany

Zühlsdorf, Michael, Dr • Translational Science Consulting • Bonn, Germany

EXHIBITION | SPONSORING

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ARENZIA Exploration Medicine GmbH*, GERMANY
is a German operator of proprietary research clinics specializing in first-in-patient trials (Phase IB and IIA) designed to identify the first efficacy signal of novel therapies at record speed and outstanding data quality. Through its dedicated Phase I infrastructure and streamlined, research-exclusive operational model, ARENSIA delivers significant timeline and cost reductions. Unlike traditional academic sites constrained by daily clinical duties, staffing limitations, patient competition, and lengthy contracting, ARENSIA's clinics are purpose-built for clinical research. Headquartered in Düsseldorf, Germany, ARENSIA operates 15 research clinics across the United States (Phoenix, Arizona), Europe (Romania, Bulgaria, Georgia, Moldova, and Ukraine), and Latin America (Buenos Aires, Argentina). The organization employs 800+ full-time professionals, including approximately 40% full-time physicians, and supports complex clinical development. ARENSIA covers a broad range of therapeutic areas, including oncology, immuno-inflammatory diseases, neurosciences, cardiology, respiratory medicine, dermatology, infectious diseases, gastroenterology, metabolic disorders, and ophthalmology. Recent FDA and EMA inspections without findings prove our strong culture of quality and operational excellence at ARENSIA. With 93% repeat business, ARENSIA is a trusted partner to leading pharmaceutical companies, innovative biotechs, and global CROs.

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In accordance with the recommendations of the German Medical Association (Bundesärztekammer, BÄK), the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF), as well as the provisions of the FSA Code of Conduct for Healthcare Professionals (§ 20 para. 5), financial contributions from the companies are published. The listed companies participate in the event within the framework of a service agreement. The disclosure of corporate contributions is made in the interest of maximum transparency towards participants, the public and the contributing companies. The scientific leadership confirms that the content of the event is designed to be product-neutral and that sponsors have no influence on the selection of topics, speakers or content. All amounts are stated exclusive of statutory value added tax and prior to the deduction of event-related expenses.



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Dr. Falk Pharma GmbH*, GERMANY

Research and Development

At the heart of our work lies many years of experience in pharmaceutical formulation, preclinical and clinical development. Dr Falk Pharma's teams implement development projects in close cooperation with contract research organisations.

In the field of galenics, Dr Falk Pharma has developed outstanding expertise in topically active — that is, locally acting — medicines for the intestinal tract and oesophagus. This has led, and will continue to lead, to a wide range of patents and regulatory approvals.

Multicentre studies play a crucial role in the authorisation of new medicinal products. Dr Falk Pharma's teams have extensive experience in organising large-scale multicentre trials and have established an international network of investigators over many years. This enables even complex studies to be conducted quickly and successfully.

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Nuvisan is a full-service contract research organisation (CRO) and development and manufacturing organisation (CDMO) with state-of-the-art laboratories in Germany and France.

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Founded over 40 years ago by a team of pharma industry innovators, Nuvisan has established a reputation for expertise and professionalism. Our team leaders have extensive experience in the biopharma industry, and our unique centres of excellence – for drug discovery in Berlin, formulation and GMP manufacturing in Sophia Antipolis, and our bioanalysis hub in Neu-Ulm – enable our experienced scientists to help guide and advance projects. We know how to discover, develop and bring the next generation of medicines to market. At the same time, we are committed to flexibility, transparency and collaboration in our approach, working closely with you to adapt to your individual needs, minimise risks and help deliver your project.

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is a high-quality strategic services provider dedicated to advancing drug development through rigorous pharmacometric analysis. We specialize in population pharmacokinetics and pharmacodynamics, non-compartmental analysis, dose justification, and model-informed drug development, with a track record of impactful contributions across therapeutic areas including oncology, immunology, neurology, and paediatrics.

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Richmond Pharmacology, UNITED KINGDOM

Founded in 2001, Richmond Pharmacology is a leading Contract Research Organisation (CRO) with a strong heritage in first-in-human and adaptive clinical trials. The company has conducted around 20% of all UK Phase I studies and delivered landmark research, including the first clinical trial in which a CRISPR therapy was administered through the bloodstream to edit genes inside the human body.

Today, Richmond supports global pharmaceutical, biotech, and genetic engineering partners, including top 10 pharma companies, in advancing next-generation therapies. With deep expertise in early-phase clinical development, Richmond helps accelerate the translation of innovative science into safe and effective medicines.

In 2020, Richmond established the Richmond Research Institute to expand scientific understanding of under-researched diseases and drive progress in areas of high unmet medical need.

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Sanofi-Aventis Deutschland GmbH, GERMANY

Sanofi is a research-based biopharmaceutical company that uses AI and is committed to improving people's lives and growing responsibly. We apply our deep understanding of the immune system to provide millions of people worldwide with life-saving vaccines and treatment options. Millions more could benefit from our innovative pipeline. Our employees are united by a single purpose: we explore the wonders of science to improve people's lives.

This inspires us to achieve progress and add value for our employees and society by addressing the most pressing challenges of our time in healthcare, the environment and society.

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SGS Pharma, BELGIUM*

SGS Pharma Clinical Research is a leading CRO specializing in early-stage development and functional biometrics (Phases I-IV). With a strong presence in Europe and the Americas, SGS offers a comprehensive range of clinical trial services, including full early-phase drug development consultancy, clinical project management and monitoring, biometrics, as well as medical safety and regulatory services. SGS operates its own clinical pharmacology unit in Belgium featuring a viral challenge testing facility and a phase I patient unit based in Hungary. SGS has a wealth of expertise in FIH studies, viral challenge testing, biosimilars and complex PK/PD studies with a strong therapeutic focus on Infectious Diseases, Vaccines, Respiratory, Dermatology and Oncology.

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T Health

T-HEALTH, GERMANY*

TrialComplete is an eSource and automation solution designed together with Boehringer Ingelheim, specifically for sites conducting early phase trials.

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TrialComplete is part of a suite of products supporting commercial and academic trial sites, and healthcare providers conducting all phases of trials. It includes TrialSite (a site management system with full-cost budgeting in line with EU state-aid rules, and a billing module) and the Research Portal, which allows hospital researchers to access pseudonymised data inside a secure work environment. With built-in analytics, and integrating artificial-intelligence tooling through the ModelArts development suite. This lets teams explore datasets efficiently, detect new patterns, create early-diagnosis models and design personalised treatments.

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WuXi AppTec, UNITED STATES OF AMERICA*

is a trusted partner and contributor to the pharmaceutical and life sciences industries, providing R&D and manufacturing services that help advance healthcare innovation. With operations across Asia, Europe, and North America, we offer integrated, end-to-end services through our unique CRDMO (Contract Research, Development, and Manufacturing Organization) platform. We are privileged to work alongside nearly 6,000 partners across 30+ countries, supporting their efforts to bring breakthrough treatments to patients. Guided by our vision that every drug can be made and every disease can be treated, we are committed to advancing breakthroughs for patients—one collaboration at a time.

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SPEAKERS | CHAIRS IN ALPHABETICAL ORDER

Artmeier-Brandt, Ulrike, Dr

Spezialisierte Ethik-Kommission für besondere Verfahren • Bonn, Germany



Dr Ulrike Artmeier-Brandt is a physician-scientist with dual board certification in Anaesthesiology (1998) and Clinical Pharmacology (2007). She holds a doctorate in medicine (Dr med., 1994) from Ludwig Maximilian University of Munich and participated in the postgraduate programme in public health at Heinrich Heine University Düsseldorf (2002–2004). Her academic and clinical career includes positions as a research fellow and assistant physician in anaesthesiology at the University Hospital of Würzburg and the University Hospital Witten-Herdecke. Her areas of clinical expertise include anaesthesiology, intensive care, and emergency medicine. From 2001 to 2008, Dr Artmeier-Brandt served as project leader at Bayer HealthCare AG in the Department of Clinical Pharmacology. She was responsible for the design and conduct of early-phase clinical trials (Phase I), management of the in-house clinical unit, and implementation of quality and safety oversight processes. She was also a tutor for study nurse qualification programs within the AGAH e.V. Since 2008, she has worked as an independent scientific consultant and managing director of abc.GbR. Since 2010, she has been a scientific advisor to the Ethics Committee of the Bavarian Medical Association, where she evaluates clinical trials under the German Medicinal Products Act (AMG), EU Clinical Trials Regulation (CTR), Medical Device Regulation (MDR), and In Vitro Diagnostic Regulation (IVDR). She also advises on research projects under §15 of the German Medical Code of Conduct.

Since 23 June 2025, she is the chair of the new founded specialised ethics committee for special procedures.

Dr Artmeier-Brandt is an active member of the German Society for Pharmaceutical Medicine (DGPharMed) and the Association for Applied Human Pharmacology (AGAH).

Baumann, Sybille, Dr

CRS Clinical Research Group Berlin • Berlin, Germany



Dr Sybille Baumann is medical doctor by profession and holds board certification as both anaesthesiology and clinical pharmacology.

Following approximately ten years of experience in anesthesiology, Sybille acquired experience in clinical trials, initially as an Investigator at the former IKP Bobenheim GmbH and later as the Deputy Medical Director at CRS Mannheim GmbH. In these roles, she conducted and oversaw phase I/IIa trials in both healthy subjects and patients, overseeing the entire process from planning until reporting. In January 2016, she assumed her current role as Medical Director at CRS Berlin GmbH, overseeing a unit with specific emphasis on First-in-Human Trials and clinical studies in women's health and dermatology.

Since 2022, Sybille has served as the President of the German Association of Applied Human Pharmacology (AGAH e.V./ Hamburg).

SPEAKERS | CHAIRS

Burghaus, Rolf, Dr
Bayer AG • Wuppertal, Germany



Rolf Burghaus studied physics at the Heinrich-Heine-University Düsseldorf, receiving his diploma in 1995. He got his doctor degree in 1997 in the field of statistical physics, followed by a stay at the Virginia Tech as a visiting researcher.

Rolf Burghaus joined the central technology division of the Bayer AG in 2000 working on Data Mining and Artificial Neural Network technologies and applications.

After changing into Bayer's Pharma division, he led the modeling and simulation department in Clinical Pharmacology, followed by the Systems Pharmacology & Medicine department in Pharmacometrics. Currently, he is leading the Virtual Patient function in the Model-Informed-Drug-Development (MIDD) organization.

Rolf Burghaus is a co-founder of Open-Systems-Pharmacology.

Cordes, Henrik, Dr
Sanofi • Frankfurt am Main, Germany



Dr Henrik Cordes is Head of Research Pharmacometrics Germany at Sanofi within the global Translational Medicine Unit. He earned his PhD from 2018 and subsequently began his career as a PK/PD modeling scientist at Boehringer Ingelheim. In 2021, he joined Sanofi and was appointed Head of Research Pharmacometrics in 2023. His group works on the digitalization of quantitative pharmacology processes with a focus on developing AI/ML methods for empirical PK/PD and mechanistic PBPK approaches.

Francke, Klaus, Dr
Bayer AG • Berlin, Germany



Dr Klaus Francke is a medical doctor and board-certified Clinical Pharmacologist with over 20 years of experience in various roles within the medical field. His professional journey includes positions as a research physician and medical consultant with Contract Research Organizations such as CRS and Parexel. Additionally, Dr Francke has worked at the health authority GKV-SV/GBA, where he gained valuable insights into healthcare regulation and drug pricing. For the past eight years, Dr Francke has served as an Early Clinical Lead in the Research and Development department at Bayer, focusing on early clinical trials. His extensive experience equips him to provide valuable perspectives on career development and professional advancement in CROs, health technology assessment (HTA) authorities, and the pharmaceutical industry.

SPEAKERS | CHAIRS

Gopalakrishnan, Sathej, Dr
Merck KGaA • Darmstadt, Germany



Dr Sathej Gopalakrishnan is currently employed at Merck Healthcare KGaA, Germany, as Senior Director and Global Head of Pharmacometrics and Systems Pharmacology. Previously, he has served as a Clinical Pharmacology Lead at Merck. Sathej is passionate about applying quantitative approaches spanning across Pharmacometrics, PBPK and QSP modeling to impact drug development. He received his PhD in Systems Biology with a thesis on mathematical modeling of viral dynamics under the Graduate Research Training Program PharMetrX at University of Potsdam, Germany.

Höchel, Joachim, Dr
Bayer AG • Berlin, Germany



Joachim Höchel is clinical pharmacologist at Bayer and has worked for more than 25 years in diverse areas of pharmacokinetics, most of these in preclinical and clinical development of new medicines. His focus areas include the efficient and comprehensive characterization of the pharmacokinetic and pharmacodynamic properties and the dose-exposure-response relationship of new medicines as well as drug-drug interactions. Joachim Höchel has authored and co-authored more than 75 peer-reviewed scientific articles and has been regularly invited to present at scientific conferences. Since 2023, Joachim Höchel has been member of the board and currently serves as President of AGAH.

Ince, Ibrahim, Dr
Boehringer Ingelheim Pharma GmbH & CO. KG • Ingelheim am Rhein, Germany



Currently heading the PBPK and QSP Modelling team at the department Clinical Pharmacology and Non-Clinical Safety at Boehringer Ingelheim, he has a PhD in Pharmacology and Pharmacometrics, with over 17 years of pharmacometrics experience. Before joining Boehringer Ingelheim in 2023, he has worked at LAP&P Consultancy as PK-PD modeling consultant, and at Bayer AG as PBPK modeling expert and pharmacometrics lead, where he was involved in the clinical development of 11 compounds. Ibrahim has (co-)published 23 peer-reviewed scientific papers, he is an active member of the Open Systems Pharmacology (OSP) management team and conference team, and member of the editorial board of the Journal of Clinical and Translational Research. Throughout his career he has significantly contributed to an improved understanding of drug pharmacology in the pediatric population.

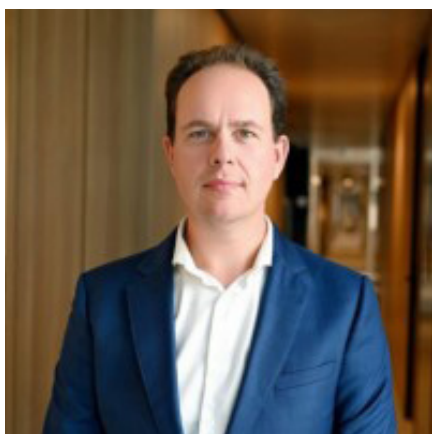
SPEAKERS | CHAIRS

Kerlin, Burkhard
Bayer AG • Wuppertal, Germany



Burkhard Kerlin has a Master of Science in Clinical Research and has been contributing to the conduct of clinical studies in various positions for the last 30 years. After stations in ward management for sites in Phase 1 to 3, project management for a Phase 1 unit and study management on the sponsor side, he found his sweet spot in heading Bayer's Early Medical Writing department, where he was able to elaborate on the standardization and simplification of increasingly complex study designs, mainly in the early phase of the clinical development. Burkhard Kerlin is burning for successful cross-functional communication and collaboration, translating and moderating needs and demands between the various stakeholders of clinical studies. Being a member of and lecturer for the AGAH since the early 2000s, he has taken been elected AGAH regent in 2023.

Klein, Jelle, Dr
SGS Belgium NV • Antwerpen, Belgium



Dr Jelle Klein graduated as Medical Doctor in 2016 from the University of Antwerp with a Master of Science in Medicine and received board certification as specialist Pharmaceutical Medicine and Clinical Pharmacology in 2024. In October 2018, Dr Klein joined the SGS Phase I unit as Principal Investigator, gaining experience in the coordination and set-up of early phase clinical trials (in different areas as immunology, neurology, cardiology, etc.) while being responsible of the safety and wellbeing of the subjects on site as well as the analysis of the clinical data. Mid 2021, Dr Klein assumed the responsibility as Associate Medical Director at SGS CPU, supporting the CPU Medical Director in the creation of strategies supporting business innovations, specialization in therapeutic area of focus. Since mid 2022, he is CPU Medical Director, and overall responsible for medical and scientific aspects of the CPU early phase projects and interaction with other sites, Belgian authorities, and organizations like Healixia and EUFEMED.

SPEAKERS | CHAIRS

Klingmann, Ingrid, Dr
Pharmaplex bv • Wezembeek-Oppem, Belgium



Physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior medical, operational and managerial functions in pharmaceutical industry, CROs and clinical trial sites with focus on clinical trial design and management, ethical and regulatory aspects. Since January 2003 she has her own pharmaceutical development and site management support consulting company. Dr Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). Her broad professional background as physician with experience in patient care, clinical development, site management, regulatory affairs, clinical research ethics, and patient engagement enables Dr Klingmann to bridge the gaps between the interests and skills of all different stakeholders in medicines development with the aim to develop new patient-relevant treatments more efficiently. Having been a founding member of EUPATI, the European Patients Academy on Therapeutic Innovation, she has been and is working on numerous activities to enable and facilitate patient involvement in medicines development in practical terms through patient and sponsor education and guidance development. Since 2023 she is Co-Chair of EU-X-CT, the multi-stakeholder initiative to enable cross-border access to clinical trials for patients and investigators in Europe. Dr Klingmann is currently also Vice-President of PharmaTrain Federation, the not-for-profit organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences and President of EUFEMED, the European Federation of Exploratory Medicines. She also teaches on different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, Germany, University of Basel, Switzerland, and the Université Libre de Bruxelles, Belgium.

Kovar, Andreas, Dr
Sanofi • Frankfurt, Germany



Andreas Kovar, Ph.D., F.C.P., studied Pharmacy at the University of Tübingen. After receiving his Ph.D. at the University of Tübingen, he held there a teaching position in Medicinal Chemistry. Subsequently, he did preclinical and clinical research on PK/PD correlations with a two-year scholarship of the DFG (German Research Foundation) at the University of Florida, Gainesville, USA in the labs of Hartmut Derendorf. In 1997 he joined Merck KGaA where he held various positions in research and clinical drug development such as Global Head Clinical Pharmacology and Pharmacokinetics for Merck Serono, Geneva and Vice President for Global Exploratory Medicine Merck in Darmstadt. In 2014 he joined Sanofi Aventis as an Assoc. Vice President in Disposition, Safety and Animal Research. Since 2020 he holds the position as Head of Translational Medicine and Early Development in Frankfurt, Germany. Andreas is an elected member of AGAH's Board of Regents since 2001 and in 2020-2022 he served as president of AGAH. He is a Fellow of Clinical Pharmacology of the American College of Clinical Pharmacology, has published >40 peer reviewed papers, articles, and book chapters and presented >100 posters and presentations at scientific meetings and congresses.

SPEAKERS | CHAIRS

Leon, Cristhyne, PhD
nova IN SILICIO • Lyon, France



Cristhyne holds a PhD in Machine Learning and Bioinformatics from Université de Rennes 1 (France), where she developed innovative applications of recurrent neural networks for disease diagnosis and age estimation in infants. She began her QSP career when she joined Nova in Silico in 2021 as a QSP modeler. In this role she has worked on integrating machine learning with mechanistic modeling, contributing to the development of translational models in diverse therapeutic areas, such as immunology, oncology, and respiratory diseases. Now in the roles of Project Manager and Head of Scientific Support, she works closely with interdisciplinary teams to support advancing quantitative systems pharmacology modeling, including its integration with data-driven approaches, for translational and clinical research at Nova In Silico.

Lippert, Jörg, Dr
Bayer AG • Leverkusen, Germany



Meibohm, Bernd, Prof. Dr
University of Tennessee • Memphis, United States



Bernd Meibohm, PhD, FCP, FAAPS is a UTHSC Distinguished Professor of Pharmaceutical Sciences and Associate Dean for Research and Graduate Programs at the College of Pharmacy, The University of Tennessee Health Science Center, Memphis, Tennessee, USA. He also serves as Chair of the University of Tennessee Department of Pharmaceutical Sciences and holds the Harriet S. Van Fleet Endowed Professorship in Pharmaceutics.

Dr Meibohm received his pharmacy degree and doctorate in pharmaceuticals from Technical University Carolo-Wilhelmina, Braunschweig, Germany. After completion of a clinical pharmacology research fellowship at the University of Florida in 1997, he joined the faculty of the University of South Carolina, and in 1999 the University of Tennessee.

Dr Meibohm's scientific interests include bacterial and viral infectious diseases, pediatric pharmacotherapy and the application of pharmacometric modeling and simulation techniques in preclinical and clinical drug development, with specific focus on therapeutic proteins. His research has resulted in over 230 scientific papers and book chapters (>14,000 citations; h-index 58), three textbooks, 200 abstracts, and over 250 invited scientific presentations to national and international audiences.

Dr Meibohm is a Fellow of the American Association of Pharmaceutical Scientists (AAPS) and the American College of Clinical Pharmacology (ACCP). He was the President of ACCP 2014-2016 and served on its Board of Regents 2008-2018. He also served as 2010 Chair for the 'Pharmacokinetics, Pharmacodynamics and Drug Metabolism' section of AAPS, as 2016-2019 Member-at-Large on the Board of Directors of AAPS, and has recently completed his term as member of the Board of Trustees of the International Society of Pharmacometrics (ISoP). Dr. Meibohm is also serving as a member of the editorial advisory boards of seven peer-reviewed scientific journals, including the Journal of Clinical Pharmacology, Clinical Pharmacokinetics, and The AAPS Journal.

Mensing, Sven, Dr
AbbVie Deutschland GmbH & Co KG • Ludwigshafen am Rhein, Germany



Sven leads a group of 40 modeling and data experts supporting the most challenging modeling & simulation activities in Clinical Pharmacology at AbbVie. Using mechanistic mathematical models and advanced statistical tools, his pharmacometrics team delivers data driven assessments to optimize AbbVie's clinical development strategies for speed, size, and insight. Sven joined Abbott/AbbVie in 2008 where he contributed to the success of numerous assets (including Humira, Mavyret, Venetoclax and many more) striving towards replacing the need to observe with the ability to predict by using science, math, and IT.

Sven holds a PhD in Medical Informatics from the University of Heidelberg and a master's degree in Biomathematics from the University of Greifswald. Sven was named Senior Research Fellow in 2023.

SPEAKERS | CHAIRS

Mikus, Gerd, Prof. Dr
Freie Universität Berlin • Berlin, Germany



Prof. Mikus received his degrees in Physics (MSc) and Medicine (MD) from the University of Bonn, Germany. He has worked as a clinical pharmacology researcher in institutes (IKP, Stuttgart), universities (Adelaide, Basel) and university hospitals (Heidelberg, Basel). In 1999, he moved to the University of Heidelberg to become the head of the Department's Clinical Research Unit (KliPS). Since then he has conducted > 100 clinical trials with almost half of them as principle investigator and more than fifteen first-in-human studies have been successfully carried out in patients and volunteers since 2007. He retired from the positions deputy head of department and head of Clinical Research Unit in 2020. He currently holds a part time position as senior scientist at the Dept. of Clinical Pharmacy & Biochemistry, Institute of Pharmacy, Freie Universitaet Berlin.

His main research was focueess on the individualisation of drug therapy by applying phenotyping and genotyping methodologies. Microdosing of CYP probe drugs have been tested in various patient groups including cancer, palliative care patients and children.

He is an active member of several scientific societies, served as AGAH president from 2004 to 2008, also a long-term member and deputy head of the Ethics Committee of the State Chamber of Physicians (Baden-Württemberg). He has published 298 peer reviewed articles; his h-index is currently 54.

Müller, Fabian, Dr
Boehringer Ingelheim Pharma GmbH & Co. KG • Biberach an der Riß, Germany



PD Dr. Fabian Müller is a board-certified Clinical Pharmacologist with extensive experience in early drug development. He currently works as a Scientific Expert in Clinical Pharmacology at Boehringer Ingelheim, contributing to early drug development projects in the therapeutic area of Eye Health. His previous roles include strategic leadership of early clinical trials in the therapeutic area of Mental Health and serving as interim head of the Human Pharmacology Center, Boehringer Ingelheim's phase I unit. He is also a university lecturer at Erlangen University and an expert in transporter-mediated drug-drug interactions. PD Dr. Müller is passionate about people development, learning, and innovation in early drug development.

SPEAKERS | CHAIRS

Riedel, Claudia, Dr

Bundesinstitut für Arzneimittel und Medizinprodukte • Bonn, Germany



Doctor, clinical pharmacologist

With BfArM since 2001

2009 Head of the Off-Label Commission Office and KAKJ

Since 2016 Head of Clinical Trials

Since 2020 Head of Clinical Trials Specialist Group

Schaller, Stephan, Dr

ESQLabs GmbH • Satterland, Germany



Dr Stephan Schaller is a systems scientist advancing model-informed drug development, precision medicine, and next-generation chemical risk assessment. With a Ph.D. in Computational Engineering from RWTH Aachen and training in Systems Biology and Control Systems Engineering, he has pioneered computational tools for personalized healthcare and risk assessment. He has held scientific roles at Bayer HealthCare and Sanofi-Aventis, and is the founder of ESQLabs GmbH, where he develops open-source, globally adopted modeling platforms. His work—spanning industry, academia, and international research consortia—champions open science as a global public good, accelerating innovation, collaboration, and equitable access to advanced computational life sciences.

Schlender, Jan, Dr

Novartis • Basel, Switzerland



Jan Schlender is Director and Site Head for Modeling & Simulation at Novartis in Basel, where he leads a multidisciplinary team encompassing Quantitative Systems Pharmacology (QSP), Translational PK/PD, Biophysical, and PBPK modeling. His work focuses on integrating mechanistic modeling approaches to support drug development and regulatory interactions across various therapeutic areas. Prior to Novartis, he spent ten years at Bayer Pharmaceuticals, holding various positions of increasing responsibility within the Modeling & Simulation and Pharmacometrics department. He studied pharmacy at the University of Bonn, National Taiwan University, and the University of Florida, and earned his PhD in Clinical Pharmacy from the University of Bonn in collaboration with Bayer Technology Services.

SPEAKERS | CHAIRS

Schneider, Annika, Dr
Bayer AG • Leverkusen, Germany



Dr Annika Schneider is PBPK Leader within the Model-Informed Drug Development department at Bayer AG. She earned her PhD for her work on „Model-informed Treatment Optimization of Liver Cirrhosis Patients“ from RWTH Aachen University in collaboration with Bayer AG. Since 2021, Annika has been working in model-informed drug development, specializing in Physiologically Based Pharmacokinetic (PBPK) modeling. In 2024, she has taken on the role of PBPK Leader.

Schultz-Heienbrok, Robert, Dr
Charité Research Organisation GmbH • Berlin, Germany



Robert Schultz-Heienbrok studied Medical Biology at the University of Amsterdam (MSc in 1999), Regulatory Affairs at the University of Cardiff (MSc in 2012) and Management at ESMT in Berlin (MBA 2017). After his PhD in Biochemistry at Free University of Berlin in 2004, he worked as a Consultant in Regulatory Affairs and Drug Development, founded the German affiliate of the Life Science Consultancy Xendo and grew the company as managing director from 1 – 30 employees. In 2017 he took a Sabbatical to write a book on drug regulations for the lay public (“Arzneimittel verstehen – Die Kunst, aus Risiken Nutzen zu machen”). In 2018 he joined the medical technology company Cerus and learned everything on the development and regulations of blood products. Since 2020 he is Director Scientific Service at Charité Research Organisation GmbH and with his team responsible for risk assessments, medical writing, scientific integrity and regulatory approvals of early clinical development trials. When not at work he either plays Badminton or enjoys dinner with family and friends.

Sjörögen, Erik, Prof. Dr
Pharmetheus AB • Uppsala, Sweden



Dr Erik Sjörögen serves as a principal consultant and the Scientific Lead for the PBPK/PBBM-Platform at Pharmetheus. His research is centered on mechanistic and physiologically based modeling and simulation to support drug development in all phases, adopting techniques such as physiologically based pharmacokinetic (PBPK), physiologically based biopharmaceutics modeling (PBBM), and quantitative system pharmacology (QSP). In addition to his role at Pharmetheus, he serves as an Associate Professor in Biopharmaceutics at the Department of Pharmaceutical Biosciences at Uppsala University.

Stemmler, Torsten, Dr

Bundesinstitut für Arzneimittel und Medizinprodukte • Köln, Germany



Dr Torsten Stemmler is head of GCP inspections unit at the Federal Institute for Drugs and Medical Devices (BfArM). He has been involved in GCP inspections since 2017 and has contributed to various European guidelines (e.g. Guideline on computerised systems and electronic data in clinical trials). He has a background in data management and neurobiology (specialising in psychophysics). He is currently working on GCP inspections and artificial intelligence in the EMA eSubgroup.

Täubel, Jörg, Dr

Richmond Pharmacology • President-elect AGAH • London, United Kingdom



Dr Jorg Taubel is medical practitioner and CEO of Richmond Pharmacology, a centre of excellence for experimental medicine studies, which he co-founded in 2001. A specialist in clinical pharmacology, Dr Taubel has extensive experience in cardiology, neurology, gastroenterology, and ethnic bridging studies. He was Principal Investigator in over 500 clinical trials in Phases 1 – 3. He is an MHRA recognised investigator for First in Human trials involving healthy and/or patient participants. Most recently Dr Taubel has dosed the first patient in the pioneering global FIH study of NTLA-2001, the first CRISPR-Cas9 in vivo gene editing for transthyretin (TTR) amyloidosis. Working in close collaboration with Professor Julian Gillmore at Royal Free Hospital, Dr Taubel has enrolled the largest cohort of ATTR heart failure patients in five clinical studies. Dr Taubel also established the Richmond Research Institute, a not-for-profit organisation dedicated to academic research to improve and save lives.

Vogl, Silvia, Dr

Paul-Ehrlich-Institut • Langen, Germany



Dr Silvia Vogl is a Senior Quality Assessor for ATMP in the Department Hematology, Cell and Gene therapy at the Paul-Ehrlich-Institut and is thus involved in the assessment of MAA and clinical trial applications as well as EMA and national Scientific Advice procedures. She also supports national GMP inspections as an expert. Additionally, Dr Vogl is responsible for assessing performance study applications for companion diagnostics (CDx) developed for ATMP. Furthermore, she is actively engaged in the COMBINE project, an initiative of the Member States' competent authorities for clinical trials and medical devices and the European Commission aiming to analyse the root causes of the challenges encountered by sponsors in conducting combined studies and identifying possible solutions.

SPEAKERS | CHAIRS

Wind, Sven, Dr

Boehringer Ingelheim Pharma GmbH & Co. KG • Ingelheim am Rhein, Germany



Position: Clinical Pharmacology Lead, Team lead Oncology; Clinical Pharmacology and Safety Science at Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany

- Study and Project Pharmacokineticist for various oncology and non-oncology projects at Dept of DMPK, Boehringer Ingelheim Pharma GmbH & Co. KG, [2007-2013]
- Clinical Pharmacology Project Lead for oncology, respiratory and CNS projects at Dept of Translational Medicine and Clinical Pharmacology, Boehringer Ingelheim Pharma GmbH & Co. KG, [2013-2024]
- Teamlead of Clinical Pharmacology Oncology Team 2 at Clinical Pharmacology and Safety Science, Boehringer Ingelheim Pharma GmbH & Co. KG [since 2024]

Zühlsdorf, Michael, Dr

Translational Science Consulting • Bonn, Germany



After more than 30 years of working experience in the pharmaceutical industry covering both, research, and drug development I founded my own consulting business. My core experiences and interests are in the fields of translational research, translational development, biomarker development, stratified medicine, clinical pharmacology, co-development of drug and diagnostics, health economics, artificial intelligence and integration of real-world data.

I am running my own business as a consultant for Translational Sciences. Formerly I hold positions as Senior Translational Research Advisor for Oncology, Global Head Translational and Biomarker Research Oncology at Merck, as a Global Head of Integrative Expression Profiling at Novartis, Basel and Head of Biomarker and Pharmacogenetics at Bayer. I was holding a position as an assistant Professor of Medical Economics at the Rhenish University Cologne.

EXHIBITION

Company	Stand no.#
ARENZIA Exploratory Medicine GmbH	01
CELERION Switzerland	02
Dr. Falk Pharma GmbH	03
NUVISAN GmbH	04
SGS Belgium NV	05
T-Systems International GmbH T-Health	06
WuXi App Tec	07

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We are proud to announce the future relocation of our UK Phase 1 clinical research operations to the iREACH Health center in 2027. iREACH is a state-of-the-art clinical research center led by Queen's University Belfast, in partnership with the Belfast Health and Social Care Trust.



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