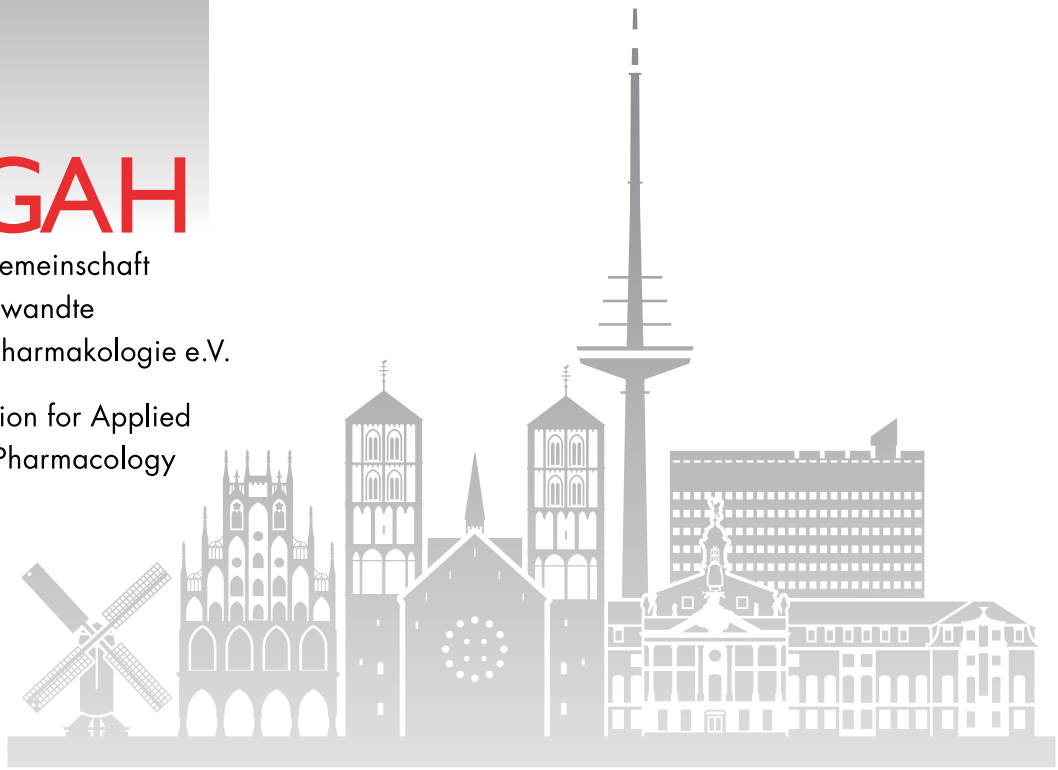
AGAH

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology



ANNUAL MEETING MÜNSTER

»ADVANCED – DIVERSE – DIGITAL: SHAPING THE FUTURE OF EARLY MEDICINES DEVELOPMENT «

18th and 19th April 2024, Münster | Germany

17th April 2024 | Pre-Meeting-Workshop

»Novel Aspects of Non-Clinical Drug Development and their translation into clinics – impact on human risk assessment«

Programme | status April 2024

Venue: Mövenpick Hotel Münster
Kardinal-von-Galen-Ring 65
48149 Münster

Pre-Meeting Workshop

Date: Wednesday, 17 April 2024

Room: Pavillon 1

Workshop language: English

AGAH Annual Meeting

Date: Thursday, 18 April and Friday, 19 April 2024

Room: Salon 3

Website: www.agah.eu

Meeting language: English

Fees:

Pre-Meeting Workshop (only)	
Member[1]	250.- Euro
Regular/Guest	300.- Euro
Junior scientist[2]	160.- Euro
Annual Meeting (only)	
Member[1]	420.- Euro
Regular/Guest	520.- Euro
Junior scientist[2]	290.- Euro
Combi Ticket	
Member[1]	580.- Euro
Regular/Guest	700.- Euro
Junior scientist[2]	390.- Euro
Conference Get-together	included

[1]of AGAH e. V., ACRON, AHPPI, AFPT-Le Club Phase I, HEALIXIA, POLFEMED
[2]under age 30

WELCOME

Dear colleagues

The broader discipline of clinical pharmacology is in the midst of a fundamental transformation: On one hand, classical Phase 1 clinical studies in healthy volunteers remain to add significant value in understanding the pharmacokinetics, pharmacodynamics, and safety of new medicines in development. On the other hand, new technologies as well as access to data and knowledge sources have matured over the recent years and are not only ready to supplement knowledge obtained in classical clinical trials, but also partly to replace it. These changes are accompanied by trends towards broader investigation of emerging treatment modalities like cell and gene therapy not warranting studies in healthy volunteers as well as regulatory changes in clinical trial approval or the desire for more diversity of the study population also in early clinical trials. The changing landscape of clinical pharmacology is therefore the main theme for this year's AGAH Annual Meeting aiming to provide insights into state-of-the-art strategies at translational stages of the development process. The conference will cover a range of aspects of the digitalization of clinical trials and clinical endpoints, assess the value of real-world data in early clinical development, give an overview on challenges and opportunities in the development of Advanced Therapy Medicinal Products (ATMPs), discuss evolving demographics in early clinical trials, and last but not least inform about news on the clinical trial authorization in Germany. As in previous years, the Annual Meeting is accompanied by a pre-meeting worshop, this year dedicated to novel aspects of non-clinical drug development and their translation into clinics. And importantly, besides the science, the AGHA Annual Meeting offers an inspiring atmosphere where attendees will be able to meet and to network with colleagues from their and neighboring disciplines.

Welcome in Münster at the AGAH Annual Meeting 2024.

Sybille Baumann President AGAH e. V.	Joachim Höchel President Elect AGAH e. V.	Andreas Kovar Past President AGAH e. V.

PROGRAMME COMMITTEE

Sybille Baumann, Berlin
Christoph Coch, Munich
Klaus Francke, Berlin
Joachim Höchel, Berlin
Christine Klipping, Berlin
Andreas Kovar, Frankfurt
Stephanie Plassmann, Basel
Jens Rengelshausen, Aachen
Barbara Schug, Oberursel
Jörg Täubel, London

WEDNESDAY, 17th APRIL 2024 · PAVILLON 1

Pre-Meeting Workshop

»Novel Aspects of Non-Clinical Drug Development and their translation into clinics – impact on human risk assessment«

Chairs	Stephanie Plassmann, Basel (CH); Jens Rengelshausen, Aachen
13:00–14:00	Safety margins in reproductive toxicology and their impact on human risk assessment: all good or do we still struggle? A critical appraisal of the recently revised ICH S5 guidance and its implementation in clinical practice Stephanie Plassmann, Basel
14:00–14:30	Break
14:30–15:15	Current regulatory requirements and the use of nonclinical pharmacological models Stephanie Plassmann, Basel (CH)
15:15–16:00	Predictivity of nonclinical models for human (examples from oncology) Michael Zühlsdorf, Bonn
16:00–16:30	Break
16:30–17:30	Modelling approaches to translate pharmacodynamics from animals to humans Rolf Burghaus, Wuppertal

18:00	Get-together (AGAH Member)
19:00	AGAH e. V. General Assembly/Mitgliederversammlung

DAY 1 · THURSDAY, 18th APRIL 2024 · SALON 3

9:30	Welcome and Introduction Sybille Baumann, Berlin

Session 1 Chairs	**Digital Endpoints in Early Clinical Development** Ruwen Böhm, Erfurt; Joachim Höchel, Berlin
9:45–10:15	Digital endpoints – an introduction to devices and regulations incl. examples of already accepted device-derived clinical endpoints Frank Kramer, Wuppertal
10:15–10:45 REMOTE	Rocky road Devices, not the ice-cream Anja Schiel, Oslo (NOR)
10:45–11:15	Using digital devices for symptom monitoring in clinical studies: Lessons learned from DIGIPD and RADAR-AD Manuel Lentzen, Sankt Augustin
11:15–11:30	Break

BREAK-OUT SESSIONS

A (Salon 3) Chairs	**Know Your Patient:** **Electronic Patient Records for Clinical Research** Klaus Francke, Berlin; Jörg Täubel, London (UK)
11:30–12:00	Opportunities and challenges in using real-world data for pharmaceutical R&D – an industry perspective Christian Diedrich, Leverkusen
12:00–12:30	Measuring contraceptive failure and pregnancy outcome in real-world data Almut Winterstein, Gainesville/Florida (USA)
12:30–13:00 REMOTE	Role of Electronic Health Records in Research in the UK - Examples from St Bartholomews Hospital London Charles Gutterridge, London (UK)

DAY 1 · THURSDAY, 18th APRIL 2024 · SALON 3

B (Pavillon 1)	**Successes and Pitfalls of Digitalization in Clinical Development**
Chairs	Martin Coenen, Bonn; Christine Klipping, Berlin
11:30–11:45	Examples for pitfalls of digitalisation in clinical trials Martin Coenen, Bonn
11:45–12:05	Regulatory aspects of virtual clinical trials Annika Dax, Oberursel
12:05–12:25	Practical aspects of virtual clinical trials Tanja Rautenberg, Berlin
12:25–12:45	Why digital tools frequently fail Stephan Herrmann, Erfurt
12:35–13:00	Discussion about pitfalls and chances of digitalization and virtual trials in clinical trials
13:00–14:15	Break
Session 2	**Advanced therapy medicinal products (ATMPs) and Clinical Pharmacology – neighbors, friends, partners or rivals?**
Chairs	Christoph Coch, Bonn; Joachim Höchel, Berlin
14:15–14:20	Session opening Session chairs
14:20–14:50	Definitions and regulatory aspects of ATMPs – what relationship can we build to overcome challenges in development? Bettina Ziegele, Langen
14:50–15:20 REMOTE	Preclinical development packages in light of regulatory requirements and risk mitigation David Jones, Coalville (UK)
15:20–15:50 REMOTE	Advanced modalities to treat neurodegenerative disease: Cell-based therapy for Parkinson's disease. Stefan Irion, New York (US)
15:50–16:15	Break

DAY 1 · THURSDAY, 18th APRIL 2024 · SALON 3

Session 2	Continuation
16:15–16:45	Preclinical development of Palintra® for the prevention of graft-versus-host disease (GvHD) - Challenges of academic ATMP research André-René Blaudszun, Leipzig
16:45–17:15	Learnings from the development of approved ATMPs with focus on CAR-T cells, a cutting edge cancer treatment Silke Holtkamp, Bergisch Gladbach
17:15–17:45	The (future) role of Clinical Pharmacologists in ATMPs development Jörg Täubel, London (UK)
17:45–17:50	Concluding remarks Session chairs

18:00–20:30	Conference get-together

DAY 2 · FRIDAY, 19th APRIL 2024 · SALON 3

Session 3	**Evolving Demographics in Early Clinical Trials**
Chairs	Sybille Baumann, Berlin; Kerstin Breithaupt-Grögler, Frankfurt
09:00–09:25	Overview of guidelines regarding the trial population in early phase clinical trials: intrinsic and extrinsic factors Kerstin Breithaupt-Grögler, Frankfurt
09:25–10:40	Structured discussions with the audience on the following topics: Ethnicity, Women of child-bearing potential, BMI, Age, Nutritional habits Sybille Baumann, Berlin; Kerstin Breithaupt-Grögler, Frankfurt; Klaus Francke; Christine Klipping, Berlin
10:40–11:00	How does a sponsor adapt to the need of increasing diversity in early phase clinical trials? – Practical examples Klaus Francke, Berlin
11:00–11:30	Break
Session 4	**Open Forum Discussion Chances and Opportunities - Clinical Trial Authorization in Germany**
Chairs	Ingrid Klingmann, Brussels (BEL); Thomas Sudhop, Bonn
11:30–12:00	Collaboration between both competent authorities and ethics committees in clinical trial authorization Susanne Lerch, Langen
12:00–12:30	Integration of approvals and notifications in accordance with the planned changes of the Radiation Protection Act in the clinical trial authorization Claudia Riedel, Bonn
12:30–13:00	Other aspects that would help to speed-up clinical trial start in Germany in practical terms Open forum discussion with support of the session speakers on e.g., · Preparation, advice and authorization of FiH trials and integrated protocols · Standard clauses in sponsor-investigator contracts · Facilitated labelling of investigator-administered IMPs Introduction by Thomas Sudhop, Bonn, and Sybille Baumann, Berlin
13:00	Concluding Remarks Joachim Höchel, Berlin
13:15	Farewell snack

EXHIBITION

ARENSIA Exploration Medicine GmbH

NUVISAN GmbH

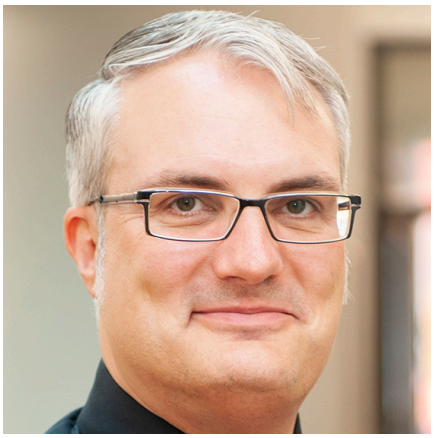
Special thanks to the exhibitors for their support!

SPEAKERS & CHAIRS IN ALPHABETICAL ORDER

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 anasthesiology, Sybille acqured 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).

Blaudszun, André-René Dr
Fraunhofer Institute for Cell Therapy and Immunology IZI • Leipzig, Germany

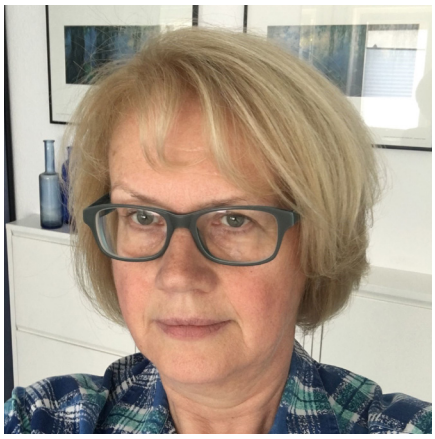


André-René Blaudszun studied biochemistry at Ruhr University Bochum and obtained his doctoral degree from Saarland University (Germany). After his postdoctoral tenure at the Center for Theragnosis of the Korea Institute of Science and Technology (KIST) in Seoul, Republic of Korea, he joined the Department of Cell and Gene Therapy Development, led by PD Dr. Stephan Fricke, at the Fraunhofer Institute for Cell Therapy and Immunology in Leipzig, Germany, in May 2019. He is the head of the In Vivo Models Unit, which investigates both active agents and cell and gene therapeutics, such as immune cells modified with chimeric antigen receptors. The unit specializes in the establishment and validation of new preclinical animal models, especially in the fields of hematology and immuno-oncology.

Böhm, Ruwen Dr
Socratec R&D GmbH • Erfurt, Germany

Ruwen Böhm studied medicine in Greifswald, Lund and Kiel and obtained his M.D. and specialisation in clinical pharmacology at the Institute of Experimental and Clinical Pharmacology in Kiel at the University Hospital Schleswig-Holstein. Since 2022, he joined SocraTec R&D GmbH as medical director. He is involved in medical education/teaching, design of clinical trials and conducting clinical trials as investigator. He is further collaborating with HMU Health and Medical University Erfurt and Friedrich Schiller University Jena. Research interests are neuropharmacology, biostatistics, digital health and early phase.

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

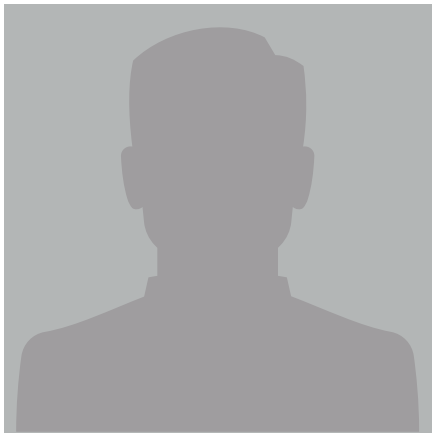


Kerstin Breithaupt-Grögler (MD, PhD) studied medicine at J.W. Goethe-University Frankfurt, Germany (1976 1983). After state approval as physician and medical thesis (doctor of medicine, summa cum laude) worked as Junior Research Fellow at Center of Physiology, University Frankfurt (1983-1985).

From 1986 to 1995 Research Physician / Clinical Investigator at Center of Cardiovascular Pharmacology, Mainz-Wiesbaden, Germany and Board Certification in Clinical Pharmacology. Since 1995 working as Independent Consultant in Clinical Pharmacology and Medical Writer. More than 30 years experience in planning, conduct, evaluation and reporting of clinical trials, writing of expert reports including clinical summaries / overviews, scientific presentation and publication (>30 original papers, >90 abstracts and oral presentations).

Founding member of the German Association of Applied Human Pharmacology (AGAH e.V., Hamburg), Board Member since 1997; President 2012-2014, Past President 2014-2018, since 2018 AGAH Regent. AGAH Delegate to EUFEMED (European Federation for Exploratory Medicines Development, Brussels). Member of scientific programme committees, conduct of workshops and conferences, training courses in exploratory medicines development and good clinical practice, qualification of study teams.

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 and now is head of Systems Pharmacology & Medicine in Pharmacometrics. Rolf Burghaus is a co-founder of Open-Systems-Pharmacology.

SPEAKERS & CHAIRS

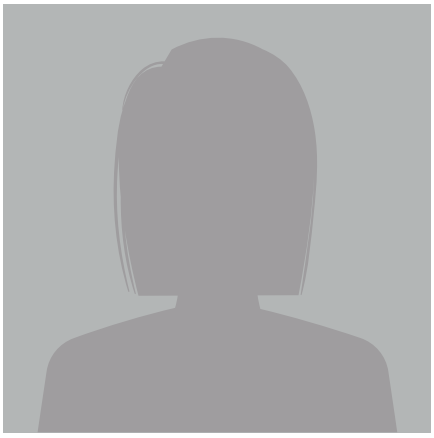
Coch, Christoph Dr
DEBRA Research • Bonn, Germany

Christoph Coch is physician and specialist in Clinical Pharmacology. After training in internal medicine, he changed 2006 to the University Hospital Bonn, where he was building up and heading the clinical trial infrastructure, including a dedicated early trial unit. In parallel, he had a research group developing treatments based on viral recognition by the innate immune system. In 2019 he became Director of Global Clinical Research at Miltenyi Biomedicine, a company focused on ATMP development. In 2021 he co-founded the digital medicine company nextevidence GmbH, which he let as CEO until 2023. Then, he started his current position as Managing Director of DEBRA Research, a non-profit company dedicated to develop treatment approaches against the rare skin disease epidermolysis bullosa.

Coenen, Martin Dr
Uniklinik Bonn • Bonn, Germany

Martin Coenen (MD) is a physician specialised in internal medicine and clinical pharmacology and consultant at the Institute of Clinical Chemistry and Clinical Pharmacology at the University Hospital Bonn. After his time in internal medicine, where he conducted phase II to IV clinical trials as an investigator of the hepatology outpatient department, he became head of the phase I unit and is now also deputy head of the Clinical Study Core Unit of the Study Center Bonn (SZB). He is involved in clinical trials of phases I-III including FIM applications as Principal Investigator, but also from the sponsor perspective of IITs of the University of Bonn. He is also responsible for the clinical pharmacology outpatient department of the institute and advises clinicians in complex drug therapies.

Dax, Annika
SocraTec R&D GmbH • Oberursel, Germany

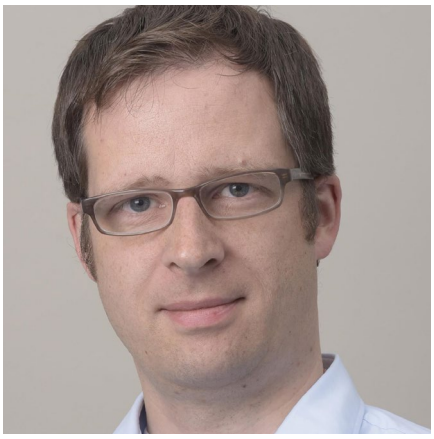


- Studied pharmacy in Frankfurt am Main (degree and license as pharmacist)
- Since 2016 Project Manager of Clinical trials at SocraTec R&D GmbH in Oberursel
- Since 2021 Head of project management at SocraTec R&D GmbH in Oberursel
- Broad experience in project management of clinical trials from study design, clinical trial application, study coordination to medical writing of the study report

- especially for phase I-III trials in mono- and multicentric settings
- with healthy volunteers and specific patient populations
- including bioavailability/bioequivalence trials

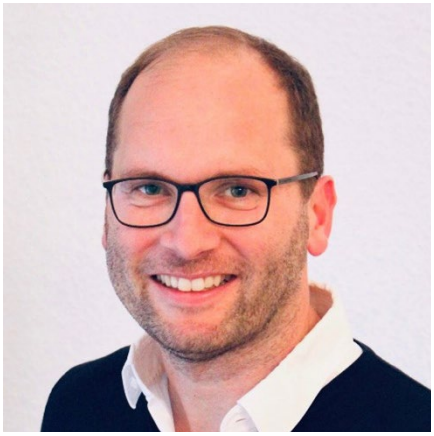
SPEAKERS & CHAIRS

Diedrich, Christian Dr
Bayer AG • Leverkusen, Germany



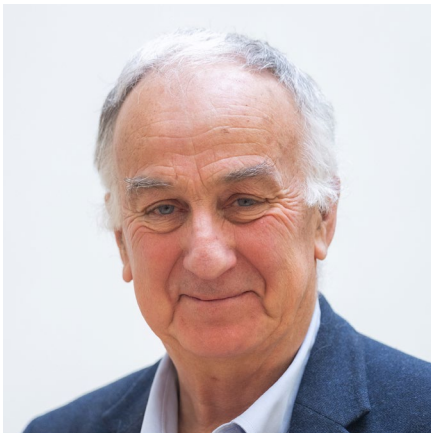
Christian Diedrich is a team head and a senior modeling and simulation expert in the pharmacometrics department of Bayer Pharmaceuticals with more than 15 years of experience in industry. Over the past 7 years, he has established a team of Real-World Data (RWD) analysis experts for generating understanding of patient populations and disease progression to address questions e.g. in the context of clinical trial design. He joined Bayer at the end of 2008 after completing postdoctoral research at the University of Warwick in the UK. Christian holds a Ph.D. in theoretical chemistry from the University of Münster.

Francke, Klaus Dr
Bayer AG • Berlin, Germany



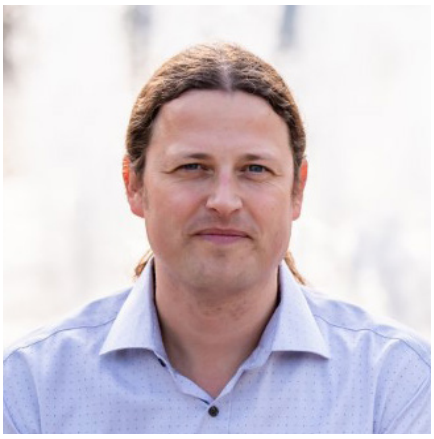
Klaus Francke is a physician and board-certified clinical pharmacologist with 20 years of professional experience in drug development and in clinical medicine. During his career he has held various positions at pharmaceutical industry, clinical medicine, academia and a regulatory health authority. Since 2017 he is working in Early Phase R&D at Bayer AG. His particular expertise is in early phase clinical studies with a strong focus on pharmacodynamic testing.

Gutterridge, Charles Dr
BARTS HEALTH NHS TRUST • London, Germany



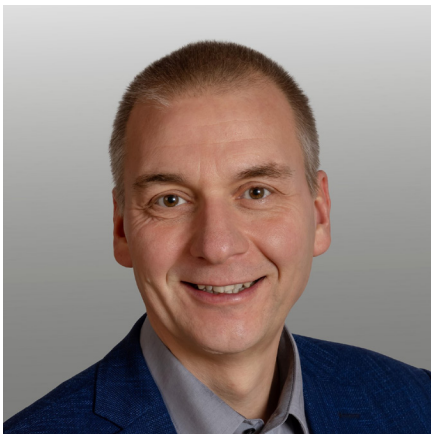
Charles is the Chief Clinical Information Officer at Barts Health NHS Trust where he works with a multi-professional team on delivering health informatics to improve patient care and great computing services for all who work at the Trust. Charles has a special interest in the use of terminologies, ontologies and natural language processing to create interoperable data and meaningful information for patients and users of health services. He has previously had leadership roles as medical director of Barts and the London NHS Trust and National Clinical Director at Connecting for Health between 2010 and 2013. He is a clinical haematologist.

Herrmann, Stephan
SocraMetrics GmbH • Erfurt, Germany



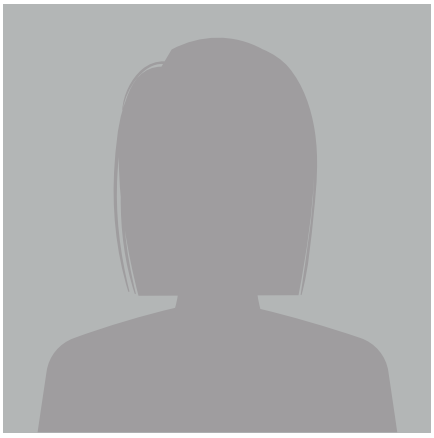
- Studied electrical engineering and computer science
- Currently works for SocraMetrics in the field of data management, biometrics and statistics
- Has more than 20 years of experience in clinical trials
- Has more than 15 years of experience in programming in regulated context
- Has more than 13 years of experience in computer system validation
- Speaks 2 languages: Customer, Programmer

Höchel, Joachim Dr
Bayer AG • Berlin, Germany

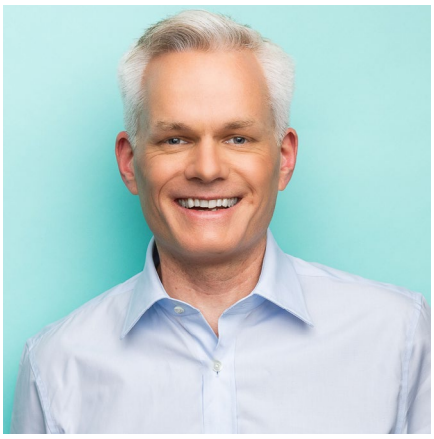


Joachim Höchel is clinical pharmacologist and has worked for more than 25 years in diverse areas of pharmacokinetics, most of these in preclinical and clinical medicine development at Bayer. His focus areas include the efficient and comprehensive characterization of the pharmacokinetic properties and the dose-exposure-response relationship of new medicines as well as drug-drug interactions. Joachim Höchel has authored and co-authored more than75 peer-reviewed scientific articles and has been regularly invited to present at scientific conferences. End of 2023, Joachim Höchel was elected as President Elect of AGAH.

Holtkamp, Silke Dr
Miltenyi Biomedicine GmbH • Bergisch Gladbach, Germany

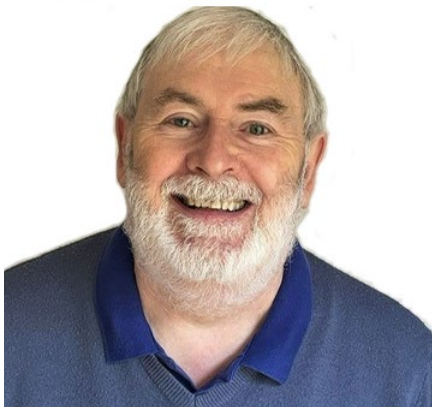


Irion, Stefan Dr
BlueRock Therapeutics • New York, USA



Stefan Irion, M.D., leads the Research organization at BlueRock Therapeutics. Since joining BlueRock in 2017, Stefan has taken on a number of roles in support of BlueRock's scientific goals; developing CNS strategy, advancing the DA01 program through IND clearance, advancing multiple neurology pipeline candidates to the next stage of development to building and expanding a cross-site and cross-functional research team. Prior to BlueRock, Stefan was part of the leadership team at Memorial Sloan Kettering that developed MSK-DA01, the current lead program at BlueRock. Stefan worked as a Senior Scientist at iPierian developing iPSCs prior to joining MSK. Stefan received his M.D. from the University of Tuebingen and did Postdoctoral Fellowship work at both Mount Sinai School of Medicine in New York and University Health Network in Toronto.

Jones, David
Coalville, United Kingdom



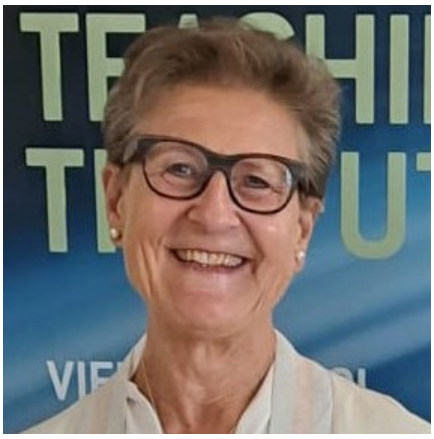
On leaving University with a BSc in Biochemistry, I joined the Huntingdon Research Centre in 1978 and spent 8 years in Contract Toxicology before moving to Fisons Pharmaceuticals, where I spent 11 years as a Toxicologist. In 1996, I joined the UK's Medicines Control Agency (MCA), which subsequently became the Medicines and Healthcare products Regulatory Agency (MHRA), where I was an Expert PharmacoToxicologist. I retired at the end of 2021 and now work as a consultant.

My primary role at MHRA principally involved assessing nonclinical data for Clinical Trial Authorisation (CTAs) Applications, both non-biological and biological. A further aspect of my job was to offer regulatory and scientific advice to companies. While the UK was part of the EU, I was the UK representative on the EU's Safety Working Party (SWP). I represented the EU at ICH on the revision of the M3 Guideline and on the ICH S10 and S11 Guidelines.

I am a Fellow of the British Toxicology Society and a Fellow of the Royal Society of Biology.

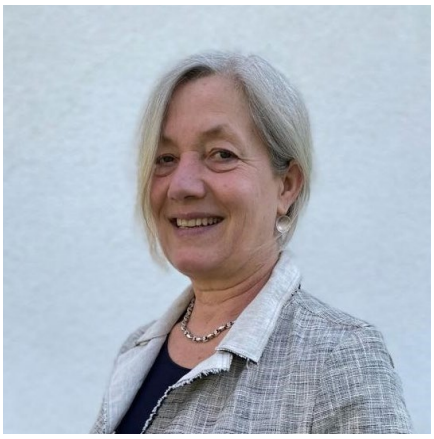
I am a guest lecturer at a number of universities and a frequent presenter at conferences around the world. I have also authored and co-authored numerous papers in various Toxicology journals.

Klingmann, Ingrid Dr
Pharmaplex b.v. • 1970 Wezembeek-Oppem, Belgien



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.
Dr Klingmann is currently also 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 Elect 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.

Klipping, Christine Dr
dinox GmbH Female Health Research • Berlin, Germany



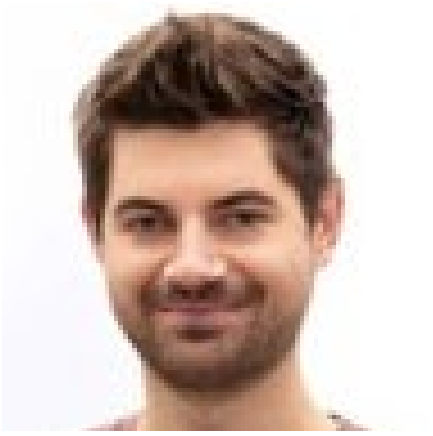
Dr Klipping, founder of dinox in 1993, has over 30 years of experience in gynecological endocrinology and in vaginal ultrasonography. She graduated in medicine in 1988, and in 1992 completed her thesis at the University of Lübeck. In 1988 and 1989 she worked as a resident at the department of Prenatal Diagnostics and Therapy, and at the department of Obstetrics and Gynecology of the University of Bonn, Germany. From 1990-1991 she was responsible for several human-pharmacology studies. In 1992 research work was continued in the Netherlands, at the department of Obstetrics and Gynecology of the Catholic University of Nijmegen. In 1993 she performed bio-equivalence and bio-availability studies at the Research Centre for Oral Contraceptives, Nijmegen, the Netherlands. In the same year Dr. Klipping founded her own independent Clinical Research Organization: dinox. Dr Klipping is frequently consulted for her know-how in gynaecological endocrinology, trial designs and related pharmacodynamic assessments. She has been extensively involved in clinical development programs for several pharmaceutical companies.

Dr Klipping is a member of several associations including the AGAH (Arbeitsgemeinschaft für Angewandte Humanpharmakologie, Germany) where she is involved as a regent.

Kramer, Frank
Bayer AG • Wuppertal, Germany

Dr. Frank Kramer acts as Director Medical Devices & eHealth at BAYER Pharmaceuticals. In his role he supports clinical development teams in the selection and implementation of Digital Health Technologies to better profile drug candidates.
Dr. Kramer is a dynamic Life Science Professional with 20+ years of experience in different leading pharmaceutical companies. He authored more than 35 publication and filed 7 patents.
Before taking over his current role he worked as Lab Head and as Director Biomarker Strategist in BAYER`s Experimental Medicine group, where he developed biomarker strategies.
Dr. Kramer obtained his Ph.D. at the University of Frankfurt, Germany and held appointments at WYETH, AVENTIS and SANOFI.

Lentzen, Manuel
Fraunhofer SCAI • Sankt Augustin, Germany



Education
2020 – present: Fraunhofer Institute for Algorithms and Scientific Computing (SCAI) & University of Bonn, Doctoral Student – Computational Life Science
2018 – 2020: Heinrich-Heine-University, Düsseldorf M.Sc. Biology
2014 – 2018: B.Sc. Quantitative Biology

Publications
2024: Lentzen, M. et al. RADAR-AD: Assessment of Multiple Remote Monitoring Technologies for Early Detection of Alzheimer's Disease. (In review)
2023: Lentzen, M. et al. A Transformer-Based Model Trained on Large Scale Claims Data for Prediction of Severe COVID-19 Disease Progression. IEEE Journal of Biomedical and Health Informatics 27, 4548–4558 (2023).
2022: Lentzen, M. et al. Critical assessment of transformer-based AI models for German clinical notes. JAMIA Open 5, ooac087 (2022).

Lerch, Susanne Dr
PEI Paul-Ehrlich-Institut • Langen, Germany

Position
Wissenschaftliche Mitarbeiterin / Scientific Officer
Fachgebiet Klinische Prüfungen / Section Clinical Trials
Paul-Ehrlich-Institut, Langen

Professional Experience
Seit / Since 04/2023: Paul-Ehrlich-Institut, Langen
Wissenschaftliche Mitarbeiterin / Scientific Officer
2007 - 2023: ICON Clinical Research GmbH, Langen
(2009 - 2011 ICON Clinical Research plc, Marlow, UK)
2017 - 2023: Clinical Risk Manager
2014 - 2017: Clinical Data Analyst
2007 - 2014: Clinical Research Associate

Training
2003 - 2007: Promotion, Dr. rer. nat.
Medizinische Hochschule & Tierärztliche Hochschule, Hannover
•PhD Studiengang Infektionsbiologie
1997 - 2003: Studium Biologie, Diplom
Johannes Gutenberg Universität, Mainz

Plassman, Stephanie Dr
PreClinical Safety (PCS) Consultants Ltd • Basel, Switzerland

Dr. med. vet. Stephanie Plassmann is a board certified specialist in veterinary pharmacology and toxicology and acts as an independent consultant for international companies and institutions since 2004. Her expertise focuses on pharmacology, non-clinical safety and drug development, both from a strategic as well as a hands-on operational perspective comprising a broad spectrum of indications from early to late stage development. She has over 30 years' experience in pharmaceutical industry and held positions including in senior management at F.Hoffmann-La Roche AG (Basel, Switzerland), Switch Biotech AG (Munich, Germany) and Morphochem AG (Munich, Germany). In 2011, she has taken over PreClinical Safety (PCS) Consultants Ltd (Basel, Switzerland), an international consultancy in all aspects of non-clinical drug development from early compound selection through to marketing approval. The company was founded in 1989.

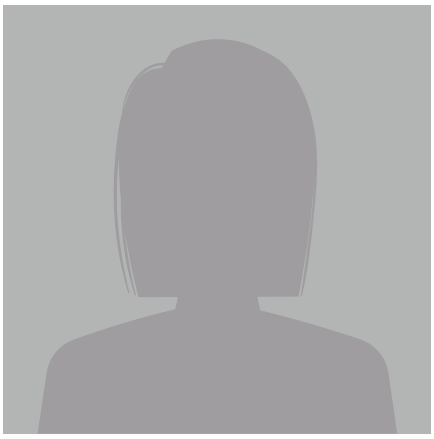
Rautenberg, Tanja
dinox GmbH Female Health Research • Berlin, Germany

Tanja Rautenberg completed her medical studies at the Freie Universität Berlin in 1994. From 1995, she worked in several hospitals and graduated as a specialist in gynecology and obstetrics in May 2008.
In 2008 she joined dinox as an Investigator and since 2011 she has performed many clinical trials phase I-III as a Principal Investigator in the research field of female health, e.g. contraception, hormonal treatment of gynecological diseases like endometriosis or hormonal replacement therapy . In 2017 she took on the responsibility as Medical Director at dinox.

Rengelshausen, Jens Dr
Uniklinik RWTH Aachen • Aachen, Germany

Dr. Jens Rengelshausen is a physician and board-certified clinical pharmacologist with more than 20 years of experience in clinical drug development and translational science. He has led respective departments in pharmaceutical industry and contributed to the development of more than 20 novel compounds in the areas of pain and inflammation focusing on early clinical trials and proof of concept. After heading back to academia, Jens currently leads clinical research on the toxicokinetics and -dynamics of occupational and environmental toxins at the Institute for Occupational, Social and Environmental Medicine at the University Hospital Aachen in Germany.

Riedel, Claudia Dr
BfArM • Bonn, Germany



Ärztin, klinische Pharmakologin

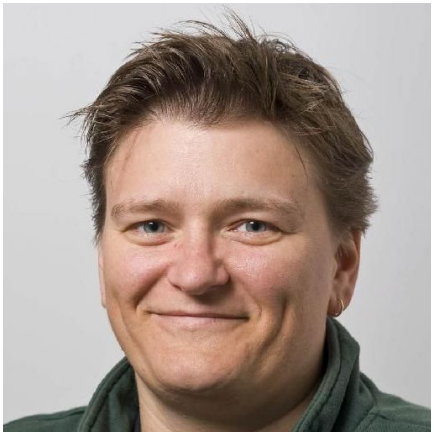
Seit 2001 im BfArM

2009 Fachgebietsleitung der Geschäftsstelle Kommission off-label und der KAKJ

Seit 2016 Fachgebietsleitung klinische Prüfung

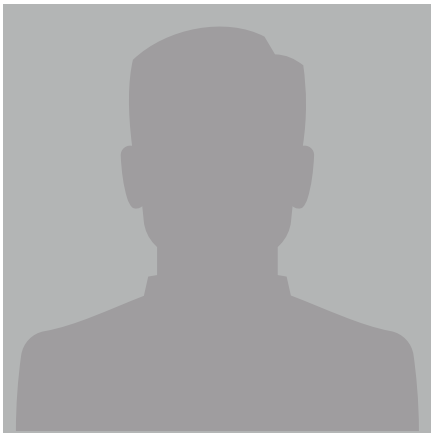
Seit 2020 Fachgruppenleitung klinische Prüfung

Schiel, Anja Dr
NOMA Norwegian Medical Products Agency • Oslo, Norway



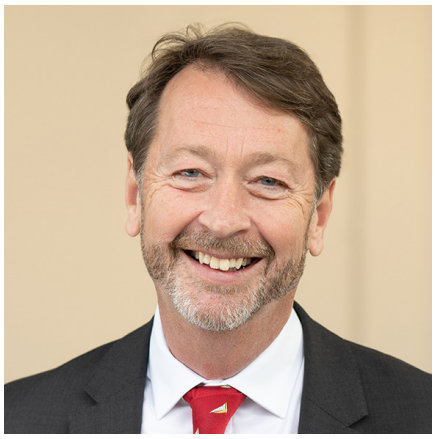
Anja Schiel has studied Biology at the Johannes Gutenberg-University, Mainz, Germany. She received her PhD from the Free University in Amsterdam in 2006 and worked several years as Post-Doc on a range of subjects focusing on oncology, immunology and molecular biology, first at the University of Leiden and later at the University of Oslo, before starting at the Norwegian Medicines Agency (NoMA) in 2012.
At NOMA (since January 2024 renamed to Norwegian Medical Products Agency) she is working as Special Adviser/Statistician/Methodologist both on regulatory and HTA projects with particular focus on early interactions with drug developers.

Sudhop, Thomas Dr
BfArM • Bonn, Germany



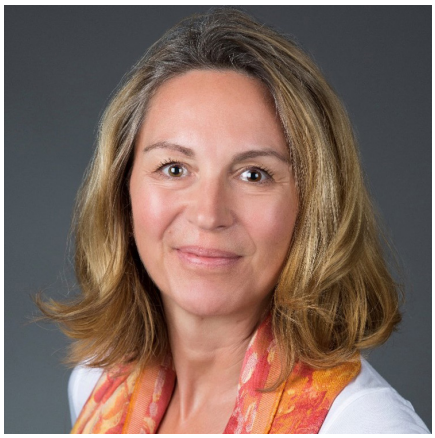
Thomas Sudhop is Director and Professor at the Federal Institute for Drugs and Medical Devices (BfArM), where he heads the Department of Information Technology and Clinical Trials. He is a trained physician and certified clinical pharmacologist as well as a private lecturer in clinical pharmacology. He attended the medical faculties in Aachen and Bonn and completed his medical studies in 1992. He was then a resident physician at the Department of General Medicine and the Department of Clinical Pharmacology at the University of Bonn and was later appointed Deputy Medical Director of the Department of Clinical Pharmacology.

Täubel, Jörg Dr
Richmond Pharmacology • London, United Kingdom



Dr. Jorg Taubel, the CEO and co-founder of Richmond Pharmacology, is a prominent figure in clinical pharmacology, with a specialisation that extends through cardiology, neurology, and more. His expertise has been pivotal in over 500 clinical trials, especially as an MHRA-recognized investigator for First in Human trials. Notably, Dr Taubel led the groundbreaking NTLA-2001 clinical trial, pioneering the use of CRISPR-Cas9 gene editing for TTR amyloidosis, marking a significant advancement in treatment options. Additionally, his commitment to medical progress is evident in founding the Richmond Research Institute, focusing on enhancing healthcare through research. His work symbolises a blend of innovation, dedication, and a drive for excellence in medical science.

Winterstein, Almut Professor
University of Florida • Gainesville, Florida, USA



Almut Winterstein is Distinguished Professor in Pharmaceutical Outcomes and Policy and in Epidemiology, and Director of the Center for Drug Evaluation and Safety at the University of Florida. Her research interests center on the post-marketing evaluation of medications and related policy using real-world data. She has chaired the FDA's Drug Safety and Risk Management Advisory Committee, served as president of the International Society of Pharmacoepidemiology and is a member of the Academy of Science, Engineering and Medicine in Florida. She received her pharmacy degree from Friedrich Wilhelm University in Bonn and her PhD in Pharmacoepidemiology from Humboldt University in Berlin.

Ziegele, Bettina
Paul-Ehrlich-Institut • Langen, Germany

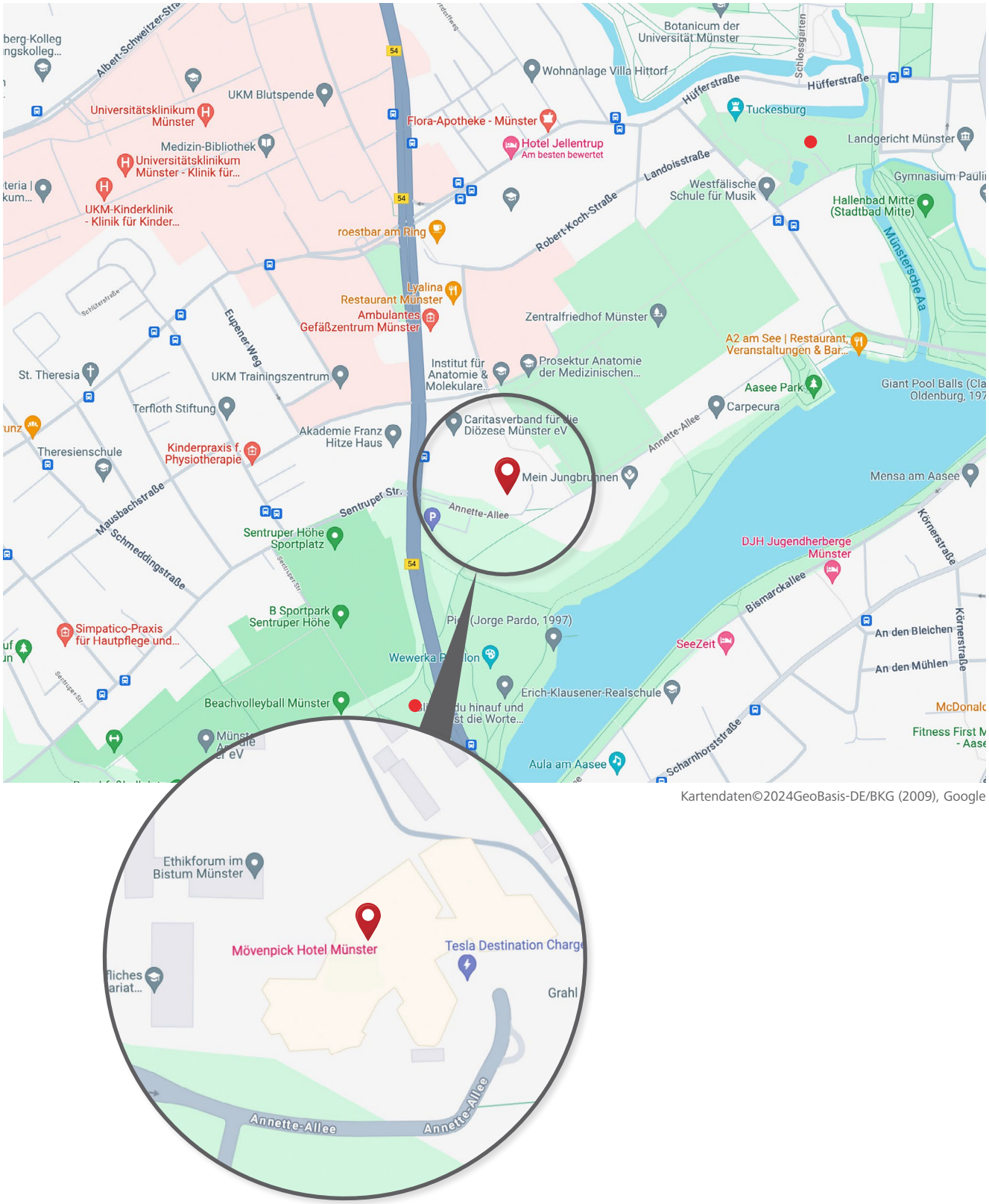
Bettina Ziegele is Liaison Officer for Stakeholder Cooperation and International Relations at the Paul-Ehrlich-Institut (PEI). She established and was the head of the PEI's Innovation Office with a focus on scientific advice for ATMP and support for SME and academia. Bettina continued to work at the Federal Ministry of Health (BMG) to improve support for the development of biotechnological innovations and was subsequently seconded to the German HTA Joint Committee (G-BA). At the European level, she is a member of the EU Innovation Network (EU-IN) at the EMA and chairs the working group for the Simultaneous National Scientific Advice (SNSA). Bettina has a master's degree in economics and philology.

Zühlsdorf, Michael Dr
Bonn, Germany

Michael is a Senior Translational Research Advisor for Oncology at Merck KGaA and consultant for Translational Medicine. Michael has more than 30 years of working experience in the pharmaceutical industry covering both, research, and drug development. His main experiences and interests are in the fields of translational research, biomarker development, stratified medicine, clinical pharmacology and the co-development of drug and diagnostics.

Formerly Michael had the positions as Global Head Translational and Biomarker Research Oncology, Global Head Clinical Pharmacology Oncology Division and PK/PD Markers at Merck. Before joining Merck he was holding positions as a Global Head of Integrative Expression Profiling at Novartis, Basel and Head of Biomarker and Pharmacogenetics at Bayer, Wuppertal.

Michael studied pharmacy at the Regina Pacis University Bonn and Chemistry at University Cologne, Germany and received its Ph.D. from the Regina Pacis University Bonn, Germany. He is the author or co-author of more than 50 scientific publications.



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Münster

Mövenpick Hotel Münster
Kardinal-von-Galen-Ring 65
48149 Münster (Germany)