BELGIAN ASSOCIATION OF PHASE-I UNITS

CLUB PHASE 1

AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

AHPPI

3rd Joint Conference of European Human Pharmacological Societies

European Competitiveness in Early Clinical Drug Development: threats and opportunities







Brussels - Belgium

20 May 2015 - Pre-conference workshop

21-22 May 2015 - Conference

www.eufemed.eu

Dear Colleague,

Welcome to Brussels and the 1st conference of the European Federation for Exploratory Medicines Development (EUFEMED)! On behalf of the four founding associations from Belgium (BAPU), France (Club Phase 1), Germany (AGAH) and the United Kingdom (AHPPI) we are proud to present to you this superb scientific programme.

This conference is not only the 1st EUFEMED conference, at the same time it is also the 3rd joint conference of four European human pharmacology associations. Indeed, after organising successful joint meetings in Berlin (2011) and Nice (2013), BAPU, Club Phase I, AGAH and AHPPI decided to join forces for more structured collaborations and recently founded the European Federation for Exploratory Medicines Development – EUFEMED. With EUFEMED a "voice" is created in the interest of exploratory medicines development in Europe.

Following the tradition of previous joint conferences, this meeting provides an excellent opportunity to hear about new developments in early clinical drug development. To that end a mixture is offered of focused scientific sessions given by experts in the field and interactive workshops providing ample time for lively discussions. The focus of this meeting is on the competitiveness of Europe in early clinical drug development, the impact of the new European regulation as well as the challenges encountered in conducting exploratory clinical studies in a continuously changing environment.

This year's conference is not only the ideal time for the inauguration of EUFEMED and for celebrating its foundation. At the same time it is also an occasion to celebrate the 10th anniversary of BAPU which is hosting this first EUFEMED conference.

As the conference takes place in the centre of Brussels, it is not only our intention to offer science. We also hope that you will enjoy a relaxed atmosphere to meet old colleagues, make new friends and get inspired by a historical city: the capital of Europe.

Many thanks for being with us in Brussels!

On behalf of the founding associations of EUFEMED,

Jan de Hoon,
BAPU

Yves Donazzolo,
Club Phase I

Hildegard Sourgens,
AGAH

Peter Dewland,
AHPPI

Scientific Committee

BAPU, Belgium: J. de Hoon, M. Raghoebar, L. Van Bortel

Club Phase I: H. Caplain, Y. Donazzolo

AGAH: K. Breithaupt, I. Klingmann, H. Sourgens, J. Taubel

AHPPI: P. Dewland, M. Hammond, U. Lorch


gsk
do more
feel better
live longer
We won't discover
all the answers
inside our own labs
The work we do in our labs is aimed at helping people through advances in science. But solving scientific challenges isn't easy and often the most successful approach is through collaboration and transparency. That's why we share our resources and expertise with partners, charities and industry peers. The ultimate goal is to achieve our mission of enabling people to do more, feel better, live longer.
Find out more at www.gsk.com
BE/COM/0003/15 – 04/2015 – V.U./E.R.
GlaxoSmithKline Pharmaceuticals s.a./n.v.
Site Apollo, Avenue Pascal, 2-4-6 1300 Wavre Belgium

Table of contents

20 May – Pre-conference workshop

Workshop 1: Implementation of the EU Clinical Trial Regulation – Opportunities and Threats to Early Medicines Development

Organisation led by AGAH and AHPPI

Location: Square - Meeting Studio 211 & 212

The upcoming Clinical Trial Regulation was primarily designed to facilitate multinational and thus late development clinical trials. But the new Regulation will apply for all types of clinical trials with medicinal products in the same way in all European countries. What will this mean for early phase trials? Will the implementation of the Regulation take into consideration the special needs of Phase I trials including: rapid approval, limited paperwork, close interaction with competent authorities and ethics committees, special requirements for multi-element trials, etc.? This workshop will focus on exchanging opinions and recommendations on optimized implementation of the single portal and the single dossier aspects for phase I trials as well as on the national implementation conditions in regulatory and ethical review that will improve or hinder future Phase I trials in Europe for pharma companies and CROs.

PROGRAMME

09:30	***Registration***
10:00	Welcome and Introduction to the Workshop: ***Ingrid Klingmann***
10:15-12:15	***Session 1: Single Portal: opportunity or burden for early medicines development?*** *Chairs: Ulrike Lorch (AHPPI) and Henri Caplain (Club Phase I)*
10:15	Keynote Presentation: Concept, compromises and implementation plan for the Single Portal ***Fergus Sweeney**, United Kingdom*
	Questions and answers
11:00	Hopes and fears for the Single Portal from a Pharma company conducting Phase I trials in Europe ***Maria-Gabriela di Matteo**, Belgium*
11:15	How will the Single Portal work for a Phase I CRO? ***Elizabeth Allen**, United Kingdom*
11:30	Needs for IT support in our National Competent Authority due to the Clinical Trial Regulation and the Single Portal ***Karina Markersen**, Denmark*
11:45	*Panel and Open Forum Discussion*
12:15-13:15	***Lunch break***

13:15-14:30	***Session 2: Single Dossier: Will national early stage trials suffer or benefit?***
	Chairs: Jan de Hoon (BAPU) and Hildegard Sourgens (AGAH)
13:15	Sponsor / CRO view
	***Bruno Speder**, Belgium*
13:30	Regulatory Authority view
	***Maria Antonia Serrano Castro, AEMPS**, Spain*
13:45	Ethics Committee view
	***Saskia de Weerd**,* The Netherlands
14:00	*Panel and Open Forum Discussion*
14:30-15:00	***Break***
15:00-18:00	***Session 3: National implementation of the Clinical Trial Regulation – how can we ensure improved conditions for early phase studies?***
	Chairs: Ingrid Klingmann (AGAH) and Annick Peremans (BAPU)
15:00	Implementation in France
	***Cécile Delval**, France*
15:30	Implementation in Belgium
	***Greet Musch** and **Kristof Bonnarens**, Belgium*
16:00-16:30	***Break***
16:30	Implementation in United Kingdom
	***Martyn Ward**, United Kingdom*
17:00	Implementation in Germany
	***Thomas Sudhop**, Germany*
17:30	*Panel and Open Forum Discussion:*
	Mutual learnings and opportunities for harmonization?
18:00	***End of the Workshop***

20 May – Pre-conference workshop

Workshop 2: An Introduction to PK/PD Modelling

Organisation led by AGAH and Club Phase I

Location: Square - Meeting Studio 202

As a professional involved in clinical pharmacology, you are fully aware of the importance of the new tools used today in drug development. Amongst them, PK/PD modeling and pharmacometrics are now essential. Therefore, you can take the opportunity of this EUFEMED conference to attend this full day workshop dedicated to PK/ PD modeling.

Whether you are a beginner or an expert in these fields, you will benefit from this staggered-approach workshop by listening and working with outstanding lecturers.

After an introductory lecture to explain the principles, you will be offered the chance to discuss first simple, then more and more sophisticated examples with our experts.

PROGRAMME

09:30	***Registration***
10:00	Welcome
10:05-12:30	***Introductory Lecture*** *Chair: Y. Donazzolo (CLUB PHASE I)*
10:05	General strategic approaches towards PK/PD modelling in clinical development ***F. Hourcade-Potelleret**, Switzerland*
11:05-11:30	***Break***
11:30	Scientific background of PK/PD modelling ***Bernd Meibohm**, USA*
12:30-13:30	***Lunch break***
13:30-15:00	***Examples of PK/PD Modelling: Interactive Session I*** *Chairs: Jens Rengelshausen (AGAH) and Kerstin Breithaupt (AGAH)*
13:30	PK/PD approach in a first-in human clinical trial for a BACE inhibitor in Alzheimer's disease ***Vassilios Aslanis** and **Florence Hourcade-Potelleret**, Switzerland*
14:15	Assessment of concentration-QT relationships in pooled Phase I trials using a real example ***Philippe Grosjean**, **Sylvain Nicolas** and **Jérôme Msihid**, France*

15:00-15:30	***Break***
15:30-18:00	***Examples of PK/PD Modelling: Interactive Session II*** *Chairs: Henri Caplain (CLUB PHASE I) and Walter Janssens (FAMHP), Belgium*
15:30	PK/PD modelling and simulation in paediatric development programs ***Akash Khandelwal**, Germany*
16:15	PK/PD modeling and simulation for efficacy and safety of corticosteroids in asthma and inflammation ***Hartmut Derendorf**, USA*
17:00	Pop PK/PD modelling of methylphenidate accounting for placebo response and Tachyphylaxis ***Roberto Gomeni**, France*
17:45	Wrap up and end of meeting

Thursday 21 May 2015 – morning

08:00	***Registration***
08:30-08:45	***Welcome and introduction to the 3rd Joint Conference of European Human Pharmacological societies: Jan de Hoon, BAPU chairman hosting the meeting***
08:45-10:15	***Session 1: What does the future of phase I research look like in Europe?***
	Chairs: Kerstin Breithaupt (AGAH) and Yves Donazzolo (CLUB PHASE I)
08:45	New transparency rules in early phase non-therapeutic trials. Open forum discussion introduced by ***Ulrike Lorch**, United Kingdom*
09:30	The new EU regulation: an asset for early drug development in Europe? Open forum discussion introduced by ***Clara Heering**, Belgium*
10:15-10:45	***Coffee break***
10:45-12:45	***Session 2: Global challenges in early development of medicines***
	Chairs: Hildegard Sourgens (AGAH) and Michael Hammond (AHPPI)
10:45	Overcoming challenges in early drug development: optimizing CNS Drug discovery using neuroimaging ***Richard Hargreaves**, USA*
11:15	Overcoming challenges in early drug development: focus on biologicals ***Michael Hamann**, Switzerland*
11:45	RNA interference (RNAi) as a therapeutic modality: From worms to flies and now humans ***Akshay Vaishnaw**, USA*
12:15	Drug-drug interactions between biologicals and small molecules ***Bernd Meibohm**, USA*
12:45-14:00	***Lunch break***

Thursday 21 May 2015 – afternoon

14:00-15:30	***4 parallel workshops*** *repeated on the 2nd day*
	1. Neuroimaging versus CSF sampling as a scientific tool in human pharmacology ***Mark Schmidt****, Belgium and* ***Ilan Rabiner****, United Kingdom*
	2. GCP and GMP inspections in phase I: what can be learned? ***Barbara Schug****, Germany and representative of FAGG*
	3. How statistical tools can help your proof of concept studies. ***Sylvain Nicolas****, France and* ***Francois Vandenhende****, Belgium*
	4. Outlook on the upcoming medical device and in vitro diagnostics regulations in the EU ***Eric Klasen****, Switzerland and* ***Ingrid Klingmann****, Belgium*
15:30	***Coffee break***
16:00-17:30	***Session 3: European setting for early drug development in special populations*** *Chairs: Omer Van Schoor (BAPU) and Peter Dewland (AHPPI)*
16:00	Pediatric drug development - do we need a PIP so early in development? American versus European approach ***Angelika Joos****, Belgium*
16:30	Specifics of early orphan drug development in Europe ***Khazal Paradis****, The Netherlands*
17:00	Revisiting the pharmacokinetics in patients with impaired renal function in the light of the latest FDA and EMA guidelines ***Eric Legangneux****, France and* ***Kasra Shakeri-Nejad****, Germany*
17:30	***End of day 1***
19:30	***Conference dinner in Hotel Le Plaza, Brussels*** *With surprise event at the occasion of the 10th anniversary of BAPU kindly offered by* ***BAPU****.*

Friday 22 May – morning

08:30	***Registration***
09:00-11:00	***Session 4: Clever approaches to navigating research challenges*** *Chairs: Jörg Taubel (AGAH) and Henri Caplain (Club Phase I)*
09:00	To what extent are "challenge agents" acceptable? ***Jan de Hoon**, Belgium*
09:30	Optimisation strategies in the design of early oncology studies ***Christophe Massard**, France*
10:00	Non-clinical and early clinical development of nanobodies ***Erik Depla**, Belgium*
10:30	Foundation of the European Federation for Exploratory Medicines Development: EUFEMED
11:00-11:30	***Coffee break***
11:30-13:00	**4 parallel workshops** already presented on the 1st day will now be repeated 1. Neuroimaging versus CSF sampling as a scientific tool in human pharmacology. ***Mark Schmidt,** Belgium and **Ilan Rabiner**, United Kingdom* 2. GCP and GMP inspections in phase I: what can be learned? ***Barbara Schug**, Germany and representative of FAGG* 3. How statistical tools can help your proof of concept studies. ***Sylvain Nicolas**, France and **Francois Vandenhende**, Belgium* 4. Outlook on the upcoming medical device and in vitro diagnostics regulations in the EU ***Eric Klasen**, Switzerland and **Ingrid Klingmann**, Belgium*
13:00	***Lunch break***

Friday 22 May – afternoon

14:00-16:00	***Session 5: Development of biosimilars: why is Europe the place to be?*** *Chairs: Barbara Schug (AGAH) and Luc Van Bortel (BAPU)*
14:00	Biosimilar development: advantages of the European environment: scientific challenges and implications ***Paul Declerck**, Belgium*
14:30	Establishing biosimilarity: the primary contribution of analytical comparability data to the totality of evidence ***Paul Chamberlain**, Germany*
15:00	Clinical strategies for global biosimilar development: a European perspective with a focus on monoclonal antibodies ***Diane Seimetz**, Germany*
15:30	Safety concerns with early clinical development of biologicals and biosimilars: clinical relevance of anti-drug antibodies ***Huub Schellekens**, The Netherlands*
16:00	Panel discussion: safety issues regarding biologicals/biosimilars development
16:15	Closing remarks
16:30	***End of the conference***

ARENSIA
EXPLORATORY MEDICINE

OUTSTANDING RECRUITMENT RATES FOR PHASE I/ II/ PROOF OF CONCEPT CLINICAL TRIALS IN PATIENTS

ARENSIA EXPLORATORY MEDICINE is a German research company specialized to address a strategic market niche: the performance of complex exploratory clinical trials in PATIENTS at high RECRUITMENT speed. The projects are performed in own, modern Phase I units located in large university hospitals in Eastern Europe.

ARENSIA serves following therapeutic areas:

IMMUNO-INFLAMMATORY, CARDIOVASCULAR, DIABETES/METABOLIC, DERMATOLOGY, RESPIRATORY, HEPATOLOGY, NEPHROLOGY, GASTROENTEROLOGY, ONCOLOGY, INFECTIOUS DISEASES HCV/HIV, UROLOGY, NEUROLOGY, PSYCHIATRY, OPHTALMOLOGY

ARENSIA OFFERS FOLLOWING SERVICES:

- Regulatory Support
- Clinical Conduct
- Project Management
- Monitoring
- Scientific Consultancy
- Quality Assurance

TYPE OF STUDIES:

▶ **Exploratory studies (SAD, MAD) with various patient populations:**

- Phase 0 trials (non-compound) / biomarker research
- First into Patient studies: complex PK/PD, hospitalization
- Safety / Efficacy / dose finding
- PROOF OF CONCEPT
- Sub-studies with exploratory design within Phase II-III

▶ **Phase I PK studies with renal and hepatic impaired patients (all stages) and the matching healthy volunteers**

info@arensia-em.com

www.arensia-em.com

Speakers

In alphabetical order

Elizabeth Allen

Having graduated from the Welsh School of Pharmacy in 1976 (B Pharm. Hons., Class 1) and completed a PhD in Drug Metabolism and Disposition in Experimental Renal Failure in 1982, I was appointed to the Department of Pharmacology and Therapeutics in the School of Medicine (formerly UWCM), University of Cardiff. Working with Professor Alan Richens and Professor Philip Routledge I was involved in the set up of an academic clinical research unit performing industry sponsored clinical studies in healthy subjects and patients.

In 1989 I joined Guy's Drug Research Unit (now Quintiles Drug Research Unit) and designed and conducted clinical studies with new molecular entities in early phase clinical development. The unit has performed over 400 First in Human studies and is internationally recognised for its expertise in delivering innovative and complex study designs.

Following the Parexel incident in March 2006, I was invited to make a formal presentation to the Expert Scientific Group (Duff Committee) on behalf of the Contract Clinical Research Organisation (CCRA) and together with Professor Mant to the MHRA Committee on Human Medicines on CHM on Phase 1.

I have been involved in designing training courses in clinical pharmacology for the Institute of Clinical Research and have academic teaching commitments with KCL, Cardiff and Cranfield Universities .

In addition to research, I am a registered UK Pharmacist and a Qualified Person and have published over 40 articles relating to Clinical Pharmacology and Human Toxicology.

Wednesday 20 May - 11:15-11:30 "How will the Single Portal work for a Phase I CRO?" in Session 1 on Single Portal: opportunity or burden for early medicines development?

Vassilios Aslanis, PharmD

Manager, Clinical Pharmacology Expert, Novartis Oncology

Vassilios Aslanis holds a Doctorate in Pharmaceutical Sciences from the University of Toulouse, France (2003), and a Master in Pharmacokinetics and Drug Metabolism from the University of Paris, France (2004). After gaining experience in Clinical Pharmacy at the Toulouse Cancer Center, he joined Pierre Fabre Pharmaceuticals in Castres, France, as Clinical Pharmacokinetics Project Manager responsible for the design, analysis, interpretation, and reporting of clinical pharmacokinetic studies for the development of cytotoxic compounds in the area of solid and hematological tumors. In 2009 he joined the Clinical Pharmacokinetic Department of Novartis Institutes for Biomedical Research in Basel, Switzerland and participated in the development of novel entities in the area of neurological and neurogenerative disorders. In June 2013 he was appointed Clinical Pharmacology Expert in the Oncology Business Unit of Novartis responsible for Clinical Pharmacology components of targeted anticancer therapy development programs.

Wednesday 20 May - 13:30-14:15 "PK/PD approach in a first-in human clinical trial for a BACE inhibitor in Alzheimer's disease" in Interactive Session 1: Examples of PK/PD Modelling

Kristof Bonnarens

Kristof Bonnarens obtained a degree of Industrial Pharmacist in 2001 at the University of Ghent. After a short career in the Pharmaceutical Industry, he joined the R&D department within the Federal Agency of Medicines and Health Products in January 2005. He acted as the ad-interim Head of Division of the Division R&D since February 2009, and was confirmed as Head of Division in 2012.

Kristof is a member of the Clinical trials facilitation group and is the FAMHP's alternate member in the European Commission's Ad Hoc Group on Clinical Trials. Since 2009, he acts as the secretary for the Clinical Trials Facilitation Group.

From July 2012 onward, he was involved as an expert in the negations of the new Clinical Trials Regulation at the level of the European Council. At the moment, he is representing the FAMHP at the group implementing the European Portal, and is a member of the steering committee for the implementation of the Clinical Trial Regulation in Belgium.

Wednesday 20 May - 15:30-16:00 "Implementation in Belgium "in Session 3 on National implementation of the Clinical Trial Regulation - how can we ensure improved conditions for early phase studies?

Paul Chamberlain

Paul Chamberlain is a biopharmaceutical development specialist with experience in analyzing structure-activity and structure-immunogenicity relationships of therapeutic proteins. He occupied different roles in R&D at SmithKline Beecham before becoming a European Regulatory Specialist at Amgen, and then Senior Director of Drug Development Programs at MDS Pharma Services. He has been directly involved in the development of biosimilar products since 2001, and is currently an Associate at Biopharma Excellence (www.biopharma-excellence.com).

Friday 22 May - 14:30-15:00 "Establishing biosimilarity: the primary contribution of analytical comparability data to the totality of evidence" in Session 5: Development of biosimilars: why is Europe the place to be?

Jan de Hoon

After obtaining a Master's degree in Chemical Sciences Jan de Hoon was trained as a MD and specialised in General Internal Medicine at the University of Leuven. Subsequently, he became a certified Clinical Pharmacologist and obtained a PhD in Medical Sciences.

Jan has 20 years of experience in clinical pharmacology, partly in industry, partly in academia. He has a special interest in early clinical drug development including exploratory clinical trials, first-in-man, imaging and biomarker studies.

He is chairman of the Belgian Association of Phase I Units (BAPU) of which he was one of the founding members. At an international level he is member of the British Pharmacological Society, Council member for Belgium within the European Association for Clinical Pharmacology and Therapeutics (EACPT) and board member of the Dutch Society for Clinical Pharmacology and Biopharmacy.

At present, he is appointed as Full Professor in Pharmacology/Clinical Pharmacology at the Faculty of Medicine of the University of Leuven (KULeuven). Since 2000 he is heading the Center for Clinical Pharmacology, an Academic Research Organisation located in the University Hospitals of Leuven near Brussels.

Friday 22 May - 09:00-09:30 "To what extent are "challenge agents" acceptable?" in Session 4: Clever approaches to navigating research challenges

Paul Declerck

Professor Paul Declerck obtained a Ph.D. in Pharmaceutical Sciences from the KU Leuven (Belgium) in 1984. After a post-doctoral training at the Rockefeller University (NY) he joined in 1986 the Center for Molecular and Vascular Biology at the KU Leuven. In 1991 he was appointed professor of Pharmaceutical Biotechnology at the Faculty of Pharmaceutical Sciences. He is research director of the laboratory for Therapeutic and Diagnostic Antibodies (KU Leuven). His research is focused on structure-function relationships of (recombinant) proteins and on the development of monoclonal antibodies for research, diagnostic and therapeutic purposes. He is Vice-President of the Commission of Medicines for human use of the Belgian Federal Agency for Medicines and Health Products, Dean of the faculty of Pharmaceutical Sciences (KU Leuven) and president of the International Society for Fibrinolysis and Proteolysis.

Friday 22 May - 14:00-14:30 "Biosimilar development: advantages of the European environment: scientific challenges and implications " in Session 5: Development of biosimilars: why is Europe the place to be?

Cécile Delval

Dr Cécile DELVAL holds and MD. She is graduated in Pharmacology.

She joined the French Health Authority A.N.S.M. (Agence Nationale de Sécurité des Médicaments) as Director of the Evaluation Division since April 2013.

At EMA, Dr Cecile Delval represents the French competent authority in different working groups related to the implementation of the EU Clinical Trials regulation.

From 2008 to 2013, Dr Cécile DELVAL was at the French Institut Pasteur as Director of the Clinical Research Department where she acted as director of the training course "Clinical research on human beings and applied ethics".

Her experience in the pharmaceutical industry (16 years at Sanofi Aventis) and in the French Authority for Health (5 years) have proven her expertise in extensive managerial as well as technical and regulatory experience in Drug Evaluation.

At Sanofi Aventis, Dr Cécile DELVAL was responsible for the implementation in North, South Europe and International countries of the Global Medicine Plan for Development of Internal Medicine Products.

Wednesday 20 May - 15:00-15:30 "Implementation in France" in Session 3 on National implementation of the Clinical Trial Regulation - how can we ensure improved conditions for early phase studies?

Erik Depla

Erik Depla is holding a PhD in Biochemistry of the Catholic University Leuven (Belgium) and did post-doctoral research on viral hepatitis at the faculty of Medicine in Leuven. After a career of 11 years at Innogenetics focusing on the development of both prophylactic and therapeutic vaccines for viral infections he moved to Ablynx were he is active already for 8 years as Project Leader developing therapeutic Nanobodies predominantly within the field of infectious diseases and oncology.

Friday 22 May - 10:00-10:30 " Non-clinical and early clinical development of nanobodies" in Session 4: Clever approaches to navigating research challenges.

Hartmut Derendorf

Hartmut Derendorf is Distinguished Professor, V. Ravi Chandran Professor of Pharmaceutical Sciences and Chairman of the Department of Pharmaceutics at the University of Florida, College of Pharmacy in Gainesville. Prof. Derendorf has published over 420 scientific publications and nine textbooks in English and German. He is Editor or Associate Editor of five Journals such as the Journal of Clinical Pharmacology. Prof. Derendorf has served as President of the American College of Clinical Pharmacology (ACCP) and President of the International Society of Antiinfective Pharmacology (ISAP). He was awarded the Distinguished Research Award of ACCP, the Research Achievement Award in Clinical Science of the American Association of Pharmaceutical Sciences (AAPS), the Leadership Award of the International Society of Pharmacometrics (ISOP) and the Volwiler Award of the American Association of Colleges of Pharmacy (AACP).

Wednesday 20 May - 16:15-17:00 "PK/PD modeling and simulation for efficacy and safety of corticosteroids in asthma and inflammation" in Interactive session II: Examples of PK/PD Modelling

Saskia de Weerd

Maria-Gabriella (Gaby) Di Matteo

Regulatory & External Relations Manager

Prevention Advisor - SSO (Site Security Officer)

She has been part of the Pfizer workgroup on EU Clinical Trial Directive and has implemented the EU CT Directive in the PCRU. In early 2012, she was part of the Pharma.be and Pfizer workgroups on the new EU CT Regulation, and was providing industry point of view about the EU CT Regulation for Phase 1 trials.She is also leading the AAHRPP accreditation of the PCRUs. The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is a non-profit organisation which promotes and acknowledges high-quality research and protection of research participants. Pfizer Inc. is the first and only pharma company to be AAHRPP accredited.

Wednesday 20 May - 11:00-11:15 "Hopes and fears for the single portal from a Pharma company conducting Phase I trials in Europe " in Session 1 on Single Portal: opportunity or burden for early medicines development?

Roberto Gomeni

Roberto Gomeni, PhD, President and founder of PharmacoMetrica France a company offering global consulting services in Pharmacometrics, and Adjunct Professor, Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, Chappel Hill, NC. He was the former head of Pharmacometrics at GlaxoSmithKline R&D, King of Prussia, PA (USA). He obtained a degree in Mathematics from the University of Milano (Italy), a PhD in Pharmacokinetics and HDR from the University of Montpellier I (France). He is responsible for strategic and leveraged utilisation of model-based approach for improving efficiency in drug development projects (from lead optimisation to marketing). His current research interests are focused on the identification and on the implementation of strategies based on model-based approach to enhance drug development process, drive decision making and risk management using drug and disease progression models, clinical trial simulation, Bayesian modelling and knowledge-based computer-assisted drug development processes. He is an author of more than 160 original research papers published in international scientific journals on individual and population PK/PD analysis and mathematical modelling in drug discovery, pre-clinical and clinical pharmacology.

Wednesday 20 May - 17:00-17:45 "Pop PK/PD modelling of methylphenidate accounting for placebo response and Tachyphylaxis" in InteractivesSession II: Examples of PK/PD Modelling

Philippe Grosjean, PhD

Director, Clinical Investigations. Clinical & Exploratory Pharmacology, Sanofi R&D.

Dr Philippe Grosjean has more than 27 years of experience working in drug development for major pharmaceutical companies. He holds a PhD degree in Pharmacology from the University of Paris V, France. In his present position he serves as a Clinical Pharmacologist in the department of Clinical & Exploratory Pharmacology of Sanofi in Chilly-Mazarin, France. He is currently responsible for the strategy of early clinical development in Cardiovascular, Diabetes and Ophthalmology projects. His R&D experiences and interests include translational medicine and biomarkers, modeling & simulation, methodology and clinical investigations from early phase I to proof of concept studies. He is a lecturer at Universities of Paris V and VI.

Wednesday 20 May - 14:15-15:00 "Assessment of concentration-QT relationships in pooled Phase I trials using a real example" in Interactive Session 1: Examples of PK/PD Modelling

Michael Hamann

Michael Hamann is the Executive Director for Scientific Affairs at Amgen, the world largest independent Biotech company, based in their European Headquarter in Switzerland. He has been working for 20 years in the pharmaceutical industry, and obtained his Ph.D. in Physiology at the University of Marburg, Germany. He started with Eli Lilly in Germany in 1994 in diabetes research, and has held various management positions, including Head of Quality Assurance in manufacturing, responsibilities in Project Management and Medical Affairs. He joined Amgen in 2005 and is, in his current role, responsible for all medical communication and scientific exchange activities across all of Amgen's therapeutic areas in Europe, JAPAC and Intercontinental.

Thursday 21 May - 11:15-11:45 "Overcoming challenges in early drug development: focus on biologicals " in Session 2: Global challenges in early development of medicines

Richard Hargreaves

Previous worldwide head of imaging and discovery neuroscience at Merck and Co. Currently Vice-President Discovery Sciences at Biogen. Over 25 years of leadership experience in pharmaceutical research, drug discovery and development, translational medicine and medical imaging with an emphasis on molecular and functional CNS imaging.

Thursday 21 May - 10:45-11:15 "Overcoming challenges in early drug development: "Optimizing CNS drug discovery using neuroimaging" in Session 2: Global challenges in early development of medicines

Clara Heering

Clara Heering, MSc, MSc, is Vice President of Clinical Risk Management at ICON Plc. Clara holds degrees in Medical Biology and Risk Analysis.

Clara has extensive experience in Clinical Research, starting her career as Research Fellow at Harvard Medical School, followed by 16 years in Pfizer where she started as a CRA and grew to the role of Director of the Business Innovation Unit, followed by 6 years of senior Clinical Operations roles at large CROs.

During her Clinical Research career, Clara has been involved in many initiatives and is a seasoned designer and implementer of innovation and change; including the design and implementation of Risk Based Monitoring at ICON.

Clara is an executive, past Chair of the Board of ACRP, member of the Board of EFGCP, past theme leader at DIA Europe and has been a volunteer in multiple taskforces and initiatives over the years.

Thursday 21 May - 09:30-10:15 "The new EU regulation: an asset for early drug development in Europe? Open forum discussion." in Session 1: What does the future of phase I research look like in Europe?

Florence Hourcade-Potelleret

Florence Hourcade-Potelleret, Pharm D, PhD is currently Director, Clinical Pharmacology at Novartis Pharma AG. She provides clinical pharmacology expertise and leadership to early projects in oncology from pre-IND to proof of concept studies and line-manages a team of Clinical Pharmacologists. She partners with development colleagues to integrate prior knowledge in order to develop innovative clinical development strategies and study designs for Phase I-II clinical trials by applying the principles of model based drug development. Prior to her employment at Novartis, Dr. H-Potelleret was a Senior Pharmacometrician at F. Hoffmann-La Roche with an emphasis in cardiovascular area and oncology.

Education: Dr.F. H-Potelleret graduated with a Doctor of Pharmacy degree in Paris and received her PhD degree in Clinical Pharmacology from the University of Lyon. Dr. H-Potelleret is published in the area of pharmacometrics, pharmacology and drug research.

Wednesday 20 May - 10:05-11:05 "General strategic approaches towards PK/PD modelling in clinical development" in the Introduction to PK/PD Modelling

Angelika Joos

Angelika Joos is a licensed pharmacist. Since 2001, she is responsible for Regulatory Policy issues at Merck Sharp & Dohme's Regulatory Affairs department in Brussels. Over the past 17 years, Angelika has gained strategic as well as operational experience with all regulatory procedures and various products in different therapeutic areas.

In her current position as Executive Director, Global Regulatory Policy she is responsible for monitoring and implementing Regulatory Policies & Procedures and advising the company on Regulatory strategies.

She has over 12 years' experience in working with various trade associations and professional organisations. Since 2012 she represents MSD in the EFPIA Scientific Regulatory and Manufacturing Policy Committee. In addition, she is actively involved in international policy activities as MSD delegate in the IFPMA Regulatory & Technical Policy Committee. Her main interests are related to HTA, Clinical Trials, Pharmacovigilance and Paediatrics.

Thursday 21 May - 16:00-16:30 "Pediatric drug development - do we need a PIP so early in development? American versus European approach" in Session 3: European setting for early drug development in special populations

Akash Khandelwal

Dr Akash Khandelwal holds PhD in Pharmaceutical Sciences from North Dakota State University, USA (2006). Akash did his Postdoctoral fellowship at University of Maryland, Baltimore where he developed computational models for Biopharmaceutics Drug Disposition Classification System and various drug transporters using machine learning methods. Thereafter, he did another postdoc at Uppsala University, Sweden where he was involved in developing population PK/PD models for various therapeutic areas and novel covariate model building tools in population PK/PD analysis. Akash also worked as PK/PD consultant at Mango solutions UK. Akash is currently employed at Grünenthal GmBh in Aachen Germany as senior Pharmacometrician responsible for providing pharmacometrics contribution to trials and projects.

Wednesday 20 May - 15:30-16:15 "PK/PD modelling and simulation in paediatric development programs" in Interactive session II: Examples of PK/PD Modelling

Eric Klasen

Eric Klasen is Vice President, Regulatory Affairs and Quality with Medtronic International Trading Sàrl, Switzerland and President of Medtronic BioPharma Europe. Prior to joining Medtronic he headed up Global Drug Regulatory Affairs at Novartis Consumer Health in Nyon, Switzerland.

He has previously held the positions of Director Regulatory Compliance of Chiron Vaccines SpA, Director of QA and QC of Serono SA in Switzerland and Italy as well as Head of the Immunochemistry Department of T.N.O. Medical Biological Laboratory in Rijswijk, The Netherlands. Eric has also worked as an independent consultant to the pharmaceutical and diagnostics industries.

A native of the Netherlands, Eric holds a M.Sc. in Genetics/Molecular Biology and a B.Sc. in Biology from the University of Leiden, The Netherlands.

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 Workshop 4 "Outlook on the upcoming medical device and in vitro diagnostics regulations in the EU"

Ingrid Klingmann, MD, PhD, FFPM, FBCPM

European Forum for Good Clinical Practice (EFGCP), PHARMAPLEX bvba

Dr. med. Ingrid Klingmann specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine.

After having joined pharmaceutical industry as medical advisor, she held senior management positions in different international contract research organisations and was responsible for operational, scientific, regulatory and business aspects of international clinical research projects from Phase I to Phase IV.

Since January 2003 she has her own pharmaceutical development and site management support consulting company. For 6 years she was also CEO of two investigative sites in London, UK, performing clinical trials in acute and chronic pain as well as musculo-skeletal diseases.

Dr. Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). On behalf of EFGCP she was Coordinator of the FP7-funded ICREL Project, Work Package Leader of the FP7-funded PatientPartner Project and at presently in her consultancy of the FP7-funded paediatric "LENA" Project. She is currently President of PharmaTrain Federation, the successor organization of the IMI Project PharmaTrain where she was Coordinator, and Work Package Leader of the IMI Project EUPATI, responsible for developing the EUPATI Network, the EUPATI National Platforms and the Ethics Panel.

Dr. Klingmann chairs the clinical research module of the post-graduate Master in the Regulatory Affairs course at the University of Bonn, Germany, co-founded and is lecturer in the Diploma Course in Clinical Trial Practices at the University of Basel, Switzerland, and is lecturer in the ECPM course at University of Basel and in the Pharmed course at Université Libre de Bruxelles, Belgium.

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 Workshop 4 "Outlook on the upcoming medical device and in vitro diagnostics regulations in the EU"

Eric Legangneux

Eric Legangneux is Medical Doctor and Clinical Pharmacologist with an international experience in the Pharmaceutical Industry. His expertise is in the Clinical Pharmacology contributions to the development of compounds in Neurology and Psychiatry from pre-clinical up to registration and beyond.

Thursday 21 May 17:00-17:30 "Revisiting the pharmacokinetics in patients with impaired renal function in the light of the latest FDA and EMA guidelines " in Session 3: European setting for early drug development in special populations

Ulrike Lorch MD FRCA FFPM

Ulrike trained as an anaesthetist at St. George's Hospital in London. She is a co-founder and Medical Director of Richmond Pharmacology. Ulrike has more than 15 years' experience in conducting early phase clinical research as principal investigator and has special expertise in innovative adaptive study designs.

Ulrike is an appraiser for physicians revalidating with the UK's General Medical Council. She is a member of the Faculty's Board of Examiners and an Educational Supervisor for specialist trainees in Pharmaceutical Medicine.

Ulrike is a stakeholder representative on the UK's National Research Ethics Service Phase 1 Advisory Group, the Medicines and Healthcare Products Regulatory Agency's Clinical Trials Stakeholder Reference Group and the European Medicines Agency's European Union clinical trials portal and Union database stakeholder group. These stakeholder groups discuss, amongst others, issues concerned with the implementation of the new EU Clinical Trial Regulation and its transparency rules.

Thursday 21 May - 08:45-09:30 "New transparency rules in early phase non therapeutic trials. Open forum discussion." in Session 1: What does the future of phase I research look like in Europe?

Karina Markersen

Karina Markersen has been the head of the clinical trials unit in Danish Health and Medicines Authority since 2008.

The unit is a small interdisciplinary team responsible for authorisation and surveillance of clinical drug trials in Denmark. Currently, we focus on how to implement the clinical trials regulation and cooperate with the ethics committees in Denmark.

The team is involved in the European regulatory network as participants to the EU clinical trials information system expert group at EMA, the clinical trials facilitation group by HMA and the Ad Hoc group by the European Commission.

Prior to joining Danish Health and Medicines Authority, Karina worked with product development and innovation management at Coloplast and Radiometer.

Karina has a background as Chemical Engineer from the Technical University of Denmark and earned diplomas in innovation management and leadership.

Wednesday 20 May - 11:30-11:45 "Needs for IT support in our NCA due to the Clinical Trial Regulation and the single portal" in Session 1: Single Portal: opportunity or burden for early medicines development?

Christophe Massard MD-PhD

Christophe Massard (MD, PhD) medical oncologist, senior consultant at Drug Development department and Department of Medical Oncology, joined the faculty in 2006. He is Head in patient Unit of DDD. He received his medical degree from PARIS XI University. He completed his residency training in Paris Hospital, followed by his fellowship in medical oncology at Gustave Roussy. Dr Massard is member of ESMO, ASCO, AACR. Dr Massard is board-certified in Medical Oncology. His research interests include early clinical trials, precision medicine, GU cancers, and circulating biomarkers.

Friday 22 May - 09:30-10:00 "Optimisation strategies in the design of early oncology studies " in Session 4: Clever approaches to navigating research challenges

Bernd Meibohm

Bernd Meibohm, Ph.D., FCP

Dr. Meibohm is a 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, TN. His scientific interests include pulmonary infectious and inflammatory diseases, pediatric pharmacotherapy and the application of quantitative modeling and simulation techniques in preclinical and clinical drug development, with specific focus on therapeutic proteins. His research work has attracted more than $9 million in extramural funding as principal and co-investigator and has resulted in over 130 scientific papers and book chapters, three textbooks, 160 abstracts, and over 140 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), and he currently serves as President of ACCP.

Wednesday 20 May - 11:30-12:30 - Scientific background of PK/PD modelling

Thursday 21 May - 12:15-12:45 "Drug-drug interactions between biologicals and small molecules" in Session 2: Global challenges in early development of medicines

Greet Musch

Dr. Greet Musch holds a PhD (1990) in pharmaceutical and biomedical sciences from the University of Brussels.

Since January 2009, Dr. Greet Musch is General Director Pre-authorisation at the Federal Agency for Medicines and Health Products in Belgium.

She joined the Janssen Research Foundation for 8 years where she was responsible for the quality development labs at R&D.

Afterwards she moved to the Federal Public Health Service as senior quality assessor, and took the lead of the R&D department in April 2004 until she signed for her current position.

She is very much involved in clinical trials with medicines and devices , unmet medical need , scientific advice and evaluations , medicines for veterinary use , homeopathic and phytotherapeutic medicines and pharmacopeial activities.

Wednesday 20 May - 15:30-16:00 "Implementation issues in Belgium " in Session 3 on National implementation of the Clinical Trial Regulation - how can we ensure improved conditions for early phase studies?

Sylvain Nicolas

Sylvain Nicolas is Head of Biostatistics for Discovery and Early Development at Sanofi. This also includes early clinical development, as well as translational medicine. Since 2000 in this expanding role, he is developing knowledge and promoting the application of modern statistical methodologies and methods (eg, modeling and simulation, bayesian approaches, identification and use of biomarker).

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 - Workshop 3 "How statistical tools can help your proof of concept studies"

Khazal Paradis, MDCM

Khazal Paradis (Kaz) is a paediatric gastroenterologist/hepatologist who has been working in rare diseases for most of his professional life. He joined the industry 17 years ago and is currently heading clinical development for rare diseases for Genzyme, a Sanofi company.

Thursday 21 May - 16:30-17:00 "Specifics of early orphan drug development in Europe " in Session 3: European setting for early drug development in special populations

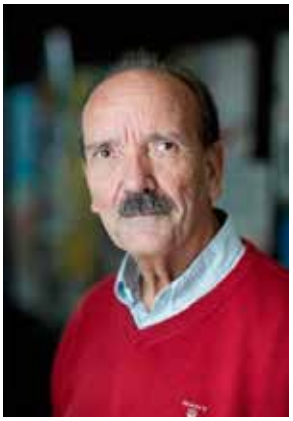
Eugenii (Ilan) A Rabiner, BSc Hons, MBBCh, FCPsych SA

Head, Imaging Applications & Chief Medical Officer, Imanova, London

Reader in Molecular Neuroimaging, Institute of Psychiatry, King's College, London

Studied medicine at the University of the Witwatersrand, Johannesburg, [BSc Hons in Physiology and Medical Biochemistry (1988) and MBBCh (1990)]. Received specialist training in psychiatry at the University of Cape Town from 1993-1997 (FCPsych SA, 1996). Trained in molecular imaging from 1997 to 2001, as a research fellow at the MRC Cyclotron Unit, Hammersmith Hospital, London (1997-2001) and spent time at the MRC Psychopharmacology Unit, University of Oxford (1997-1999). Worked on the application of molecular imaging techniques as a tool to investigate in vivo neurochemistry and psychopharmacology. Joined GlaxoSmithKline as Director in Translational Medicine and Technologies group in 2001. From 2006, Head of Clinical Imaging Applications at the GSK Clinical Imaging Centre on the Hammersmith Hospital campus in London. In 2011 transferred with the GSK Clinical Imaging Centre to form Imanova, Centre for Imaging Sciences, and took on the role of Head of Imaging Applications, and Chief Medical Officer. In 2012 appointed as Reader in Molecular Neuroimaging at the Centre for Neuroimaging Sciences, in the Institute of Psychiatry, Kings College, London. Research interests focus on the application of molecular imaging to the investigation of neurochemistry and psychopharmacology and in particular to CNS drug development.

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 Workshop 1 "Neuroimaging versus CSF sampling as a scientific tool in human pharmacology"



Huub Schellekens

Huub Schellekens, MD, PhD is professor of Pharmaceutical Biotechnology at Utrecht University in the Netherlands. He is also director of the WHO Utrecht Centre of Excellence for affordable biopharmaceuticals in low and middle income countries. He teaches Medical Biotechnology at the Department of Innovation Studies and has a research position at the Faculty of Pharmaceutical Sciences at the same university.

He is a medical microbiologist by training and works on the preclinical development of biopharmaceuticals. He published more than 400 papers in peer reviewed international journals concerning many aspects of the development of therapeutic proteins. During the last years his work has included the immunogenicity of protein drugs and the problem of biosimilars.

Prior to joining Utrecht University, he was deputy director of the Dutch Primate Center, director of Medscand Ingeny and medical microbiologist at the Reinier de Graaf Hospital in Delft the Netherlands. In 1992-1997 he coordinated a EU concerted action on the antigenicity of r-DNA derived pharmaceuticals

He studied medicine at Erasmus University in Rotterdam, The Netherlands (1967-1973). There he also did his training in Medical Microbiology (1976-1980) and received his Ph.D. in 1980.

Friday 22 May - 15:30-16:00 "Safety concerns with early clinical development of biologicals and biosimilars: clinical relevance of anti-drug antibodies " in Session 5: Development of biosimilars: why is Europe the place to be?

Mark Schmidt

Dr. Schmidt received his medical degree from the University of Chicago, entered postgraduate training in psychiatry, and later completed a clinical research fellowship at the NIMH. He has worked in neuroscience in the pharmaceutical industry for 18 years. Since joining Janssen Pharmaceutica in 2005, he has been responsible for clinical testing of NMEs from Phase 1 through proof of concept, leads preclinical imaging efforts for new imaging probe development, and leads the clinical qualification of new PET probes. He has co-authored numerous peer-reviewed manuscripts, reviews, and book chapters on in vivo imaging biomarker methods for CNS drug development.

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 Workshop 1 "Neuroimaging versus CSF sampling as a scientific tool in human pharmacology"

Barbara Schug

Dr Barbara Schug studied pharmacy at Rheinische Friedrich-Wilhelm-Universität, Bonn, she received a scholarship from the "Studienstiftung des Deutschen Volkes" and was awarded a doctor's degree for experimental pharmacological work in 1991.

In 1992 she started her professional career at Zentrallaboratorium Deutscher Apotheker, Eschborn. In 1998 she founded, together with Prof Dr Henning Blume, an independent research institute, SocraTec R&D,. In 2007 she founded SocraMetrics, an independent biometrical institute. She is currently managing shareholder in both companies.

Her area of work covers the planning and realisation of early phase (I and II) trials in healthy subjects and patients and she is also responsible for phase-III and phase-IV studies realised by her companies. This work has led to more than 80 scientific publications so far. Alongside the chemically defined medicinal substances, work is focussing on herbal medicines and biotech medicines.

Thursday 21 May -14:00-15:30 + Friday 22 May - 11:30-13:00 - Workshop 1 "GCP and GMP inspections in phase I: what can be learned?"

Diane Seimetz

Dr Seimetz has over 16 years of global drug development, regulatory affairs and partnering experience in the biopharmaceutical industry.

She is co-founder of Biopharma Excellence, a consulting company specialized in drug development, regulatory affairs and partnering strategies.

She is the former Executive Vice President and Chief Scientific Officer of Fresenius Biotech. Together with her team she developed the first bispecific, trifunctional antibody catumaxomab. After successful approval in the EU, this antibody was awarded the "Prix Galien" which honors outstanding research and innovative drug development.

She was involved in numerous due diligence projects for both, in-licensing and out-licensing strategies.

Dr Seimetz looks back on a large number of meetings with EMA, national European agencies, FDA, Health Canada, and TGA as well as other jurisdictions.

Her product portfolio knowledge covers mono- and polyclonal antibodies, recombinant proteins, complex peptides, advanced therapy medicinal products as well as medical devices. She has in-depth experience with the development and approval of new products and biosimilars.

Dr Seimetz received her degree in pharmaceutical science from the University of the Saarland and completed her PhD at the University of Heidelberg. Her research work was conducted at the German Cancer Research Center and the Johns Hopkins University, Baltimore (USA). Dr. Seimetz received her Master's Degree in Drug Regulatory Affairs from the University of Bonn.

Dr Seimetz started her professional career in 1999 within the Fresenius group. After successful set up of the Regulatory Affairs Department she was promoted to Vice President and Head of Department. From 2008 to 2013 she was as Chief Scientific Officer in charge of international drug development. She was a member the Fresenius Executive Group.

Friday 22 May - 15:00-15:30 "Clinical strategies for global biosimilar development: a European perspective with a focus on monoclonal antibodies" in Session 5: Development of biosimilars: why is Europe the place to be?

Maria Antonia Serrano Castro

- M.D. in Medicine, Universidad de Granada (Spain), 1982
- Specialist in Clinical Pharmacology, Universidad Autónoma de Madrid, 1987
- Ph.D. in Pharmacology, Madrid, Universidad Autónoma de 1989. Doctoral Degree in Medicine with Honors
- Master in Bioethics, Complutense University of Madrid, 1991.

Works for the Spanish Ministry of Health since 1987, currently as Head of Clinical Trials Division Sector at the Spanish Agency for Medicines and Medical Devices (AEMPS). She has participated as Spanish expert in the Medicines and Medical Devices Council working group during the discussions on the draft clinical trials (CT) regulation and is member of EU groups working on the applicability of the CT regulation.

Wednesday 20 May - 13:30-13:45 "Regulatory Authority view" in Session 2 on "Single Dossier: Will national early stage trials suffer or benefit?"

Bruno Speder

Bruno Speder holds a degree in bio-engineering and a degree in business economics from the University of Ghent, and has an additional degree in Health Economics from the EHSAL Management School. He joined SGS Life Science Services in 2008 and has held several positions in the regulatory group since. He is currently is Head Clinical Regulatory Affairs. He is involved in all the regulatory aspects of drug development, focusing on regulatory support to sponsors in early development phase. He has a special interest in Viral Challenge studies.

Wednesday 20 May - 13:15-13:30 - in Session 2 "Sponsor/CRO view Single Dossier: Will national early stage trials suffer or benefit? "

Thomas Sudhop, MD, Director and Professor

Director of the Division for Scientific Services at the

German Federal Institute for Drugs and Medical Devices (BfArM)

Since 2005 Thomas Sudhop is the head of the Division for Scientific Services at the German Federal Institute for Drugs and Medical Devices (BfArM) and responsible for the departments "clinical trials", "scientific advice", "legal services", "external expert panels", "pharmacopeia" and "information technology". He joined the agency in December 2004 as head of the clinical trial unit. Prior to that he was assistant medical director of the Department of Clinical Pharmacology at the University of Bonn. He receives his habilitation (venia legendi) in 2003 and became "private lecturer" (privatdocent) for "Clinical Pharmacology". He gives lectures on pharmacology, clinical pharmacology and regulatory affairs at the University of Bonn.

Thomas Sudhop holds a German specialist title in Clinical Pharmacology and was former past president of the German association for applied human pharmacology (AGAH).

Wednesday 20 May - 17:00-17:30 "Implementation in Germany" in Session 3 on National implementation of the Clinical Trial Regulation - how can we ensure improved conditions for early phase studies?

Fergus Sweeney, PhD

Head, Inspections and Human Medicines Pharmacovigilance Division

European Medicines Agency

Current Responsibilities

Fergus Sweeney is Head of Inspections and Human Medicines Pharmacovigilance Division at the European Medicines Agency. The Division is responsible for pharmacovigilance, including signal detection and management and monitoring of products on the market, and provides leadership for the Agency's pharmacovigilance system. It ensures the coordination of inspections and good practice standards. It deals with incident management in the area of safety and quality of human medicines, in liaison with the European medicines regulatory network. The division maintains close contact with international partners in the areas of inspection and pharmacovigilance in conjunction with the Agency's International Affairs function.

Brief Employment History

In 1999 Fergus joined the Agency Inspections Sector to coordinate GCP and more recently Pharmacovigilance inspections. He was appointed Head of Sector, Compliance and Inspections in May 2009 and as Head of Division Inspections and Human Pharmacovigilance in August 2013.

Fergus has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Prior to joining the Agency he worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance.

Wednesday 20 May - 10:15-11:00 - Keynote presentation: Concept, compromises and implementation plan for the Single Portal in Session 1: Single portal: Opportunity or banden(?) for early medicines development

Akshay Vaishnaw

Dr. Vaishnaw is the EVP R&D and Chief Medical Officer at Alnylam. He received his M.D. from the University of Wales College of Medicine, U.K., with training in Internal Medicine and Rheumatology, and his Ph.D. in Molecular Immunology from the University of London. Dr. Vaishnaw is a Fellow of the Royal College of Physicians (U.K.). Prior to joining Alnylam in 2006, Dr. Vaishnaw worked in the Medical Research group at Biogen Idec Inc., where he led the development of alefacept (Amevive™) to approval in psoriasis. Subsequently at Biogen, he worked in Business Development helping in license daclizumab and BG12 for MS, and then started the Translational Medicine function.

Thursday 21 May - 11:45-12:15 "RNA interference (RNAi) as a therapeutic modality: From worms, to flies and now humans " in Session 2: Global challenges in early development of medicines

Francois Vandenhende

Francois Vandenhende is the founder and CEO of ClinBAY, a statistical CRO and software company, specialized in Bayesian methods for clinical trials. Prior to establishing ClinBAY in 2007, Dr. Vandenhende was the deputy global head for early phase neuroscience and oncology statistics at Eli Lilly and Company. He has a Ph.D in statistics from UCL, Belgium.

Thursday 21 May - 14:00-15:30 + Friday 22 May - 11:30-13:00 Workshop 3 "How statistical tools can help your proof of concept studies"

Martyn Ward

Acting Group Manager

Medicines & Healthcare products Regulatory Agency (MHRA)

Dr Ward is currently acting Group Manager at the MHRA with responsibility for clinical trials, Biologicals and Parallel Imports. He qualified in medicine at St Georges Hospital, London and spent five years as a Medical Officer in the Royal Navy before completing his training as an anaesthetist. He spent five years as an anaesthetist in the NHS gaining his FRCA before joining the pharmaceutical industry in 1990.

He has held a number of positions in the pharmaceutical industry, principally involved in clinical research with big Pharma companies, leaving Novartis UK in 2004 as Director of Medical Operations. He joined the Agency as the Head of the Clinical Trials Unit in April 2004 and has also chaired the European Clinical Trials Facilitation Group (CTFG) between January 2005 and 2008 and since September 2012 has been co-chair.

He represented the UK on the EU Council Working Party negotiating the new Clinical Trials Regulation and is now actively leading the implementation in the UK.

Wednesday 20 May - 16:30-17:00 "Implementation issues in United Kingdom" in Session 3 National implementation of the Clinical Trial Regulation - how can we ensure improved conditions for early phase studies?"

Exhibition & Sponsoring

		Booth number	
Aepodia sa		11	Sponsor
ARENSIA Exploratory Medicine GmbH		3	Exhibitor
BioKinetic		14	Exhibitor
Biotrial		2	Exhibitor
Centre for Human Drug Research		9	Sponsor
CRS Clinical Research Services Andernach GmbH		5	Exhibitor
Dinox bv		7	Exhibitor
Eurofins Optimed		8	Sponsor
Nuvisan GmbH		1	Exhibitor
Parexel International GmbH		6	Sponsor

		Booth number	
Pfizer, CRU, Brussels	PFIZER CLINICAL RESEARCH UNIT BRUSSELS	13	Sponsor
QPS Netherlands, BV	QPS helps you navigate	12	Exhibitor
Richmond Pharmacology, Ltd	RICHMOND Pharmacology	10	Exhibitor
SGS Life Science Services	SGS	4	Sponsor
UCB	ucb		Sponsor

A SPECIAL THANKS FOR SUPPORTING THE CONFERENCE DINNER GOES TO

Roche

THE CONFERENCE IS ALSO SUPPORTED BY

AMGEN

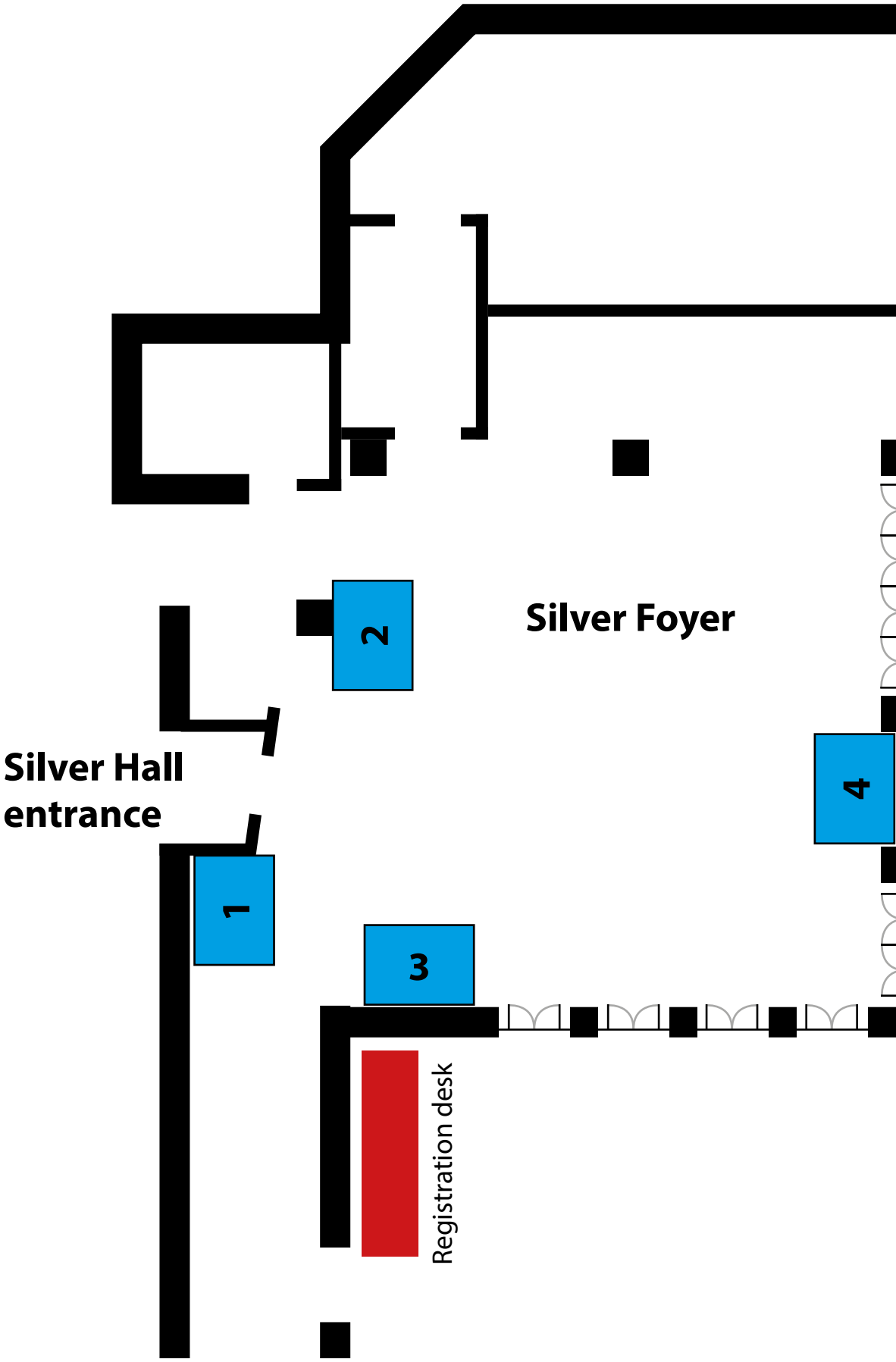
visit.brussels

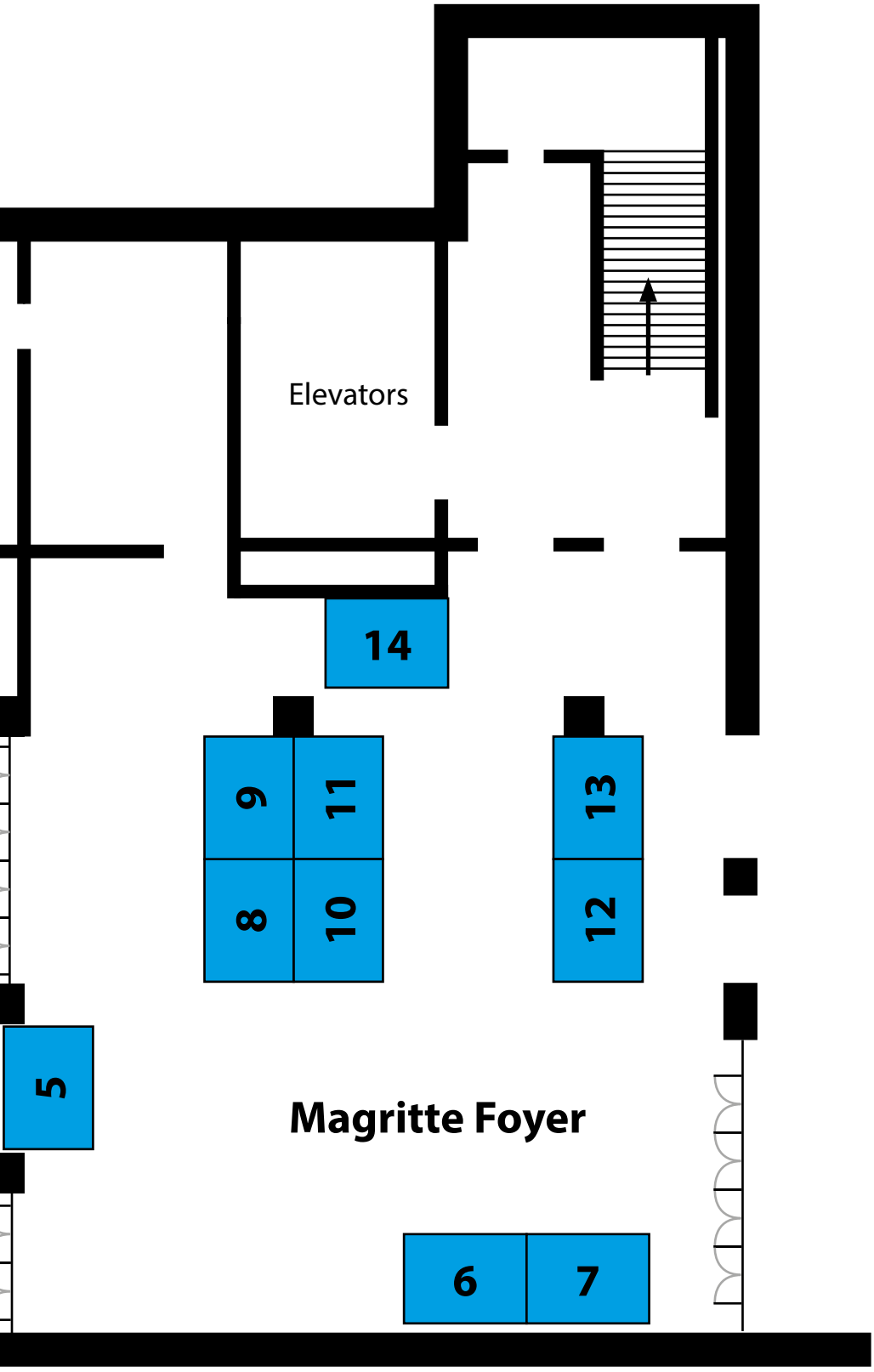
WIFI SPONSOR

RICHMOND Pharmacology

Select network *'square-guest'* Login: *joint* Password: *joint15*

Exhibition floor plan





Exhibition opening hours: ***21 May*** *10:00 – 17:30*

22 May *10:00 – 16:00*

Phase III Success
Begins with Optimized Phase I and Phase II

Use **Bayesian Statistics** to Predict the Probability of Success

Arlenda is recognized as experts in Bayesian Modeling and Statistics. Our innovative approach optimizes and predicts the outcome of late phase research.

TRANSLATIONAL SCIENCES
Connecting the dots between the information from laboratories, pre-clinical development and production to improve your clinical outcome and probability of success.

PREDICTIVE POPULATION PK / PD MODELING
Understanding the key mechanisms and relationships driving the clinical efficacy and safety of your product.

CLINICAL TRIAL SIMULATION & PREDICTION
In silico testing of different scenarios to offer you a real risk-based decision process.

ADAPTIVE & OPTIMAL DESIGNS
Optimizing the design, conduct, programming and analysis of each part of your clinical development plan.

GCP - COMPLIANT STATISTICAL EXECUTION AND REPORTING
Statistical input into clinical study protocol and reports, development of the SAP, programming and validation of Tables, Figures and Listings.

Why Risk a Failed Phase III Program?

Optimized programs dramatically improve your chances of success in late phase trials, saving millions of dollars and months or years of effort.

CONTACT US TODAY for a review of your non-clinical or clinical program and let us show you the VALUE that Bayesian methods can bring to your company.

Bruno Boulanger, CSO
bruno.boulanger@arlenda.com ▪ www.arlenda.com
Office: +32 (0)10 46 10 10 ▪ Mobile: +32 (0)476 81 39 36

Arlenda
Advance Your Business with Statistics

Notes:

We appreciate your visit to brussels and are looking forward to seeing you at the next conference!

AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

CLUB PHASE 1

BELGIAN ASSOCIATION OF PHASE-I UNITS
bapu

AHPPI
AHPPI

AGAH e.V.
Postfach 11 11
56601 Andernach
Germany

www.agah.info

Association Le Club Phase I
/sc OPTIMED
1, rue des Essarts
38610 Gieres
France
www.clubphase1.fr

BAPU vzw
Lange Beeldekensstraat 267
2060 Antwerpen
Belgium

www.bapu.be

AHPPI
PO Box 47724
London
NW10 7WW
United Kingdom
www.ahppi.org.uk

Collaboration.
Now that's what we call a medical breakthrough.

At Janssen, we seek answers to some of the toughest questions in medicine. We believe nothing is more powerful than collaboration. There should not be barriers in the pursuit of groundbreaking treatments.

Collaboration goes beyond new treatments. From early discovery to access and distribution, we seek partners who want the same things we do: better outcomes for our patients.

Our mission drives us. Our patients inspire us. We collaborate with the world for the health of everyone in it.

www.janssenpharmaceutica.com
www.jnjpharmarnd.com

Janssen Research & Development
A Division of Janssen Pharmaceutica NV

Turnhoutseweg 30, B-2340 Beerse, Belgium

janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson