



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Research and Development Support Division

## Speaker biographies

Agenda - Regulatory Workshop on Clinical Trials Designs in Neuromyelitis  
Optica (NMO) and Spectrum Disorders

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## Jan Mueller-Berghaus



Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines, Langen, Germany

### Professional CV:

Jan Mueller-Berghaus is member of the Scientific Advice Working Party (SAWP) since 2009 and in 2011 he was elected as co-opted member of the Committee for Medicinal Products for Human Use (CHMP). He is paediatrician by training and joined the Paul-Ehrlich-Institut (Germany) as clinical expert in 2005. The Paul-Ehrlich-Institut is the German Federal Agency for vaccines and biomedicines and is actively participating in all aspects of German and European marketing authorisation as well as clinical trial authorisation.

Prior experience includes basic research in immunology and translational research in the immunotherapy of cancer.

## Jackie Palace



Dr Jackie Palace is a consultant neurologist in Oxford and honorary senior clinical lecturer for Oxford University. She leads the Oxford Multiple Sclerosis group and runs a national service for congenital myasthenia and jointly a UK neuromyelitis optica service. Her MS service comprises a regional clinical service and a clinical research group. Research interests include clinical treatment trials, immunological studies, pathology, biomarkers, genetics and imaging studies on neurodegeneration and its detection and association with inflammation. She is a UK lead for the National Risk Sharing Scheme which assessed the long-term effectiveness for disease modifying agents in multiple sclerosis.

## Prof. Dr. Friedemann Paul, MD



**Current Position**      Head of Research Group „Clinical Neuroimmunology“, NeuroCure Clinical Research Center, Charité - Universitätsmedizin Berlin and Head of Research Group “Clinical and Experimental Neuroimmunology” in the Experimental and Clinical Research Center, Charité Campus Buch

### Medical Education and Career

1988 – 1995	Medical studies at the Free University of Berlin, Clinical training in France, Israel and Zimbabwe
1996 – 2001	Training in Neurology und Clinical Neurophysiology, Auguste-Viktoria-Klinikum, Berlin
2001 – 2004	Training in Epileptology und Electroencephalography, Epilepsiezentrum Berlin-Brandenburg
2002 – 2003	Training in Psychiatry, Schlosspark-Klinik Berlin
Since 2003	Resident in Neurology
Since 2004	Resident and Senior Physician, Cecilie Vogt Clinic for Neurology, Charité – Universitätsmedizin Berlin
Since 2008	Head of Research Group „Clinical Neuroimmunology“, NeuroCure Clinical Research Center, Charité – Universitätsmedizin Berlin
Since 2011	Professor of Clinical Neuroimmunology, NeuroCure Clinical Research Center, Charité – Universitätsmedizin Berlin

### Research Fields

Neuromyelitis Optica (Devic's Syndrome)

Neurodegeneration and Neuroprotection in Multiple Sclerosis (MS) and Experimental Autoimmune Encephalomyelitis (EAE)

Diagnostic Tools in Neuroimmunology (Imaging (OCT, MRI, Ultrahigh Field MRI, Ultrasound), Laboratory and CSF Biomarkers), Cognitive impairment, Sleep Disorders and Fatigue in MS

## **Brian G. Weinshenker, M.D.**

Brian G. Weinshenker is Professor of Neurology and Consultant at Mayo Clinic, Rochester MN. Dr. Weinshenker's major research interests are directed at the understanding of inflammatory demyelinating diseases of the central nervous system including multiple sclerosis including: 1) natural history of multiple sclerosis; 2) genetics of multiple sclerosis and neuromyelitis optica; and 3) classification, diagnosis, and treatment of severe inflammatory demyelinating syndromes of the central nervous system including Devic's syndrome (neuromyelitis optica). He was awarded the John J. Dystel award for multiple sclerosis research in 2011 by the American Academy of Neurology and National Multiple Sclerosis Society (USA).

## **Romain Marignier**

Romain Marignier is a MD-PhD in Neurology at the Lyon Neurological Hospital, France. His specialisation is in neuro-inflammatory disorders with a special focus on neuromyelitis optica (NMO). For the past 5 years, He has coordinated the French nationwide NMO cohort and biobank, NOMADMUS, which brings together French experts in neuro-inflammatory disorders.

Dr Marignier is also the project coordinator of the European Network EDEN "establishment and use of a European database and biological bank for research and treatment in acute neuromyelitis optica and related disorders", granted by ERANet-ERARE 2, that gathers European clinicians and scientists top-experts in the field of NMO.

Dr Marignier's research focuses on epidemiology of NMO and pathophysiology using in vitro, ex vivo and animal models, at the Lyon Neuroscience Research Centre."

## **Eliezer Katz, MD FACS**

Dr. Katz is currently senior director at RIA (respiratory, inflammation, and autoimmunity) clinical development, MedImmune Inc.

Dr. Katz joined the pharmaceutical industry in 2004 following a 20 years of academic career as a transplant surgeon. His last position in academia was associate professor of surgery and director of liver transplant at University of Massachusetts Medical Center.

In Industry, Dr. Katz was vice president at CTI clinical trial and consulting services, and senior director at Medicine Development Group, Pfizer Inc.

Dr. Katz is an author in more than 50 peer review publications.

## Luca Pani

Director General of the Italian Medicines Agency (AIFA).

Luca Pani, Medical Doctor and specialized in Psychiatry, is an Expert in Pharmacology and Molecular Biology, and a Fellow of the National Research Council of Italy and currently serves as Director General of the Italian Medicines Agency (AIFA).

Prof. Pani's professional trajectory has touched several areas of expertise from preclinical study to clinical activity as well as R&D of CNS drugs, along with his commitment to teaching and clinical activity, such as: national and international regulatory activities for the European Union; preparation, evaluation and coordination of Research Projects; Strategic Planning and partnerships with national and international Research Groups; participation in international bodies and Advisory Committees.

He is also the Italian Member of the Committee for Human Medicine Products (CHMP); Member of the Scientific Advice Working Party (SA-WP); Member of the Working Party on Central Nervous System (WP-CNS); Chair of the European Union Management Board Telematic Committee (EUMBTC); Chair of the European Risk Management Strategy Facilitation Group (ERMS-FG) of the European Medicines Agency (EMA) in London (UK).

Luca Pani is the author of over one hundred scientific publications. Editor and author of several volumes. He has attended more than 1000 conferences, seminars and national and international Roundtables as an invited speaker.

## Warren W Wasiewski MD

Dr. Wasiewski is Vice President of Clinical Development for Neurology at Alexion Pharmaceuticals and Global Medical Lead for the Neuromyelitis Optica clinical program.

He is a board certified Pediatric Neurologist with more than twenty years of clinical experience in academic and private practice. He is a former Associate Professor of Pediatrics and Neurology at Penn State University Children's Hospital.

Dr Wasiewski began his career in industry thirteen years ago as a Medical Director at Astra-Zeneca. His clinical trial experience includes all phases of clinical development across several Neurologic indications, including stroke, headache and pain.

## Bruce Cree

Bruce Cree, MD, PhD, MCR is an Associate Professor of Clinical Neurology in the Department of Neurology at the University of California San Francisco. Dr. Cree completed his MD and PhD in Biochemistry at UCSF. His neurology residency training was at Columbia University. He returned to UCSF for a Sylvia Lawry National Multiple Sclerosis Society fellowship and received a Masters in Clinical Research. He is the Clinical Research Director at the UCSF MS Center. He divides his time between patient care, clinical research and teaching. His research focuses on the genetic epidemiology of multiple sclerosis, understanding factors that contribute to disease progression and developing novel therapies for MS through clinical trials. In addition to multiple sclerosis, Dr. Cree specializes in research and care of patients with neuromyelitis optica and transverse myelitis.

## Susan VanMeter



Susan VanMeter qualified from the University of Oklahoma College of Medicine in 1991. After an internship at the University of Oklahoma College of Medicine, she completed residency at Duke University School of Medicine in the Department of Psychiatry and Behavioral Sciences. She joined faculty at Duke University in the Department of Psychiatry and Behavioral Sciences where she remained until 2003. At that time, Susan joined GlaxoSmithKline, working in drug development. She is currently a Senior Director in the Neurosciences Therapy Area at GlaxoSmithKline, leading development programs evaluating therapies for various neurologic diseases.

## Sarah Kavanagh



Sarah Kavanagh received her undergraduate degree in Biochemistry from Clemson University in 1996. After serving as a research assistant at the Medical University of South Carolina and Duke Clinical Research Institute, she received a Masters of Public Health degree in Biostatistics from the University of North Carolina at Chapel Hill in 2001. Prior to joining GlaxoSmithKline in 2007, she was employed as a statistician at Quintiles, a contract research organization. Sarah is currently a manager of statistics in the Neurosciences Therapy Area at GlaxoSmithKline, providing statistical guidance on a number of development programs evaluating therapies for various neurologic diseases.

## Irene Wilson

Irene is the UK Mastocytosis Charity Leader.

Diagnosed with Systemic Mastocytosis in 1980.

Diagnosed with Neuromyelitis Optica 2013.

## Simon Woods

Simon Woods (PhD) is Co-Director of the Policy Ethics and Life sciences Research Institute (PEALS [www.ncl.ac.uk](http://www.ncl.ac.uk)) at Newcastle University (an interdisciplinary bioethics research centre). Simon has a longstanding interest in the ethics of research; he has been a member and vice-chair of NHS research ethics committees for over 12 years and is a member of the National Research Ethics Service (NRES) National Ethics Advisors' Panel. Simon's research explores the ethical, legal and social implications (ELSI) of developments within the life sciences. Simon's recent work has a focus on translational research within rare disease and rare disease genomics. He is currently exploring the challenges of 'big data' sharing in the context of rare genetic disease. Simon is a philosophy graduate with a PhD in Bioethics.

## Wiley A. Chambers

Wiley A. Chambers, MD, is the Deputy Director of the Division of Transplant and Ophthalmology Products in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). After receiving an undergraduate degree from Colgate University, Dr. Chambers completed medical school and a residency in Ophthalmology at The George Washington University School of Medicine and Health Sciences in Washington, DC. He is currently a Clinical Professor of Ophthalmology and Adjunct Assistant Professor of Computer Medicine at The George Washington University. He joined the FDA in 1987, as a primary reviewer for ophthalmic drug products and in 1990 became a Supervisory Medical Officer for Ophthalmologic Drug Products. In this capacity, Dr. Chambers has supervisory responsibility for the clinical review of ophthalmologic drug products and ophthalmic therapeutic biologic products submitted to the Center for Drug Evaluation and Research. Additionally, Dr. Chambers is the recipient of numerous Public Health Service, FDA and Center for Drug Evaluation and Research awards for his work with the FDA and he serves as the American Academy of Ophthalmology's Delegate to United States Pharmacopeia Convention.

## Mario Miguel Rosa, MD

Member of SAWP and Geriatric Expert Group, and Clinical Assessor to CHMP at EMA;

Clinical Pharmacologist, Clinical expert for INFARMED since 1995 - Pharmacovigilance, 1998 – HTA (has been involved on CNS drugs - including MS drugs - for pharmacotherapeutic and economic assessment since 1998);

Lecturer in Clinical Pharmacology and Therapeutics, Neurology, Ethics, and Coordinator of the "Ethics in Investigation" module of Oncobiology PhD program at Lisbon Medical School;

Head of the Regional Pharmacovigilance Unit (UFLVT) of the National Pharmacovigilance System;

Investigator at the Clinical Pharmacology Unit of the Instituto de Medicina Molecular – FML (pharmacoepidemiology);

Neurology Consultant at University Hospital CHLN-FML in Lisbon, Portugal: Head of the Movement Disorders Outpatient Clinic since 2006; Clinical investigator as Subinvestigator / Investigator / National coordinator from 1990 till 2011;

Member of the Ethics Committee: at CHLN-FML since 2004 and Fundação Champalimaud since 2012 in Lisbon.

## **M Isabel Leite, MD, DPhil**

Dr Maria Isabel Leite is Honorary Neurology Consultant and Senior Clinical Research Fellow at the Oxford University Hospital and University of Oxford since 2012 and the main area of specialist interest and research is neuroimmunology, particularly antibody mediated neurological diseases, including myasthenia gravis, neuromyelitis optica and autoimmune encephalitis.

Dr Leite has just been nominated European expert for EMA, and her participation in the regulatory workshop on clinical trials designs in NMO and spectrum disorders is her first activity in an EMA initiative.

Dr Leite runs, with Dr Palace, the NMO service in Oxford, one of two national highly specialised centres for patients with NMO. She participates, with Prof Vincent, Dr Waters and Dr Woodhall, in laboratory research on NMO, and with all the clinical and laboratory team in clinical research on NMO.

Dr Leite started her laboratory research on neuroimmunology in Prof Vincent's lab in Oxford where she completed her DPhil on seronegative myasthenia gravis, where part of the studies focused on thymus pathology and another part on the detection of antibodies to clustered acetylcholine receptor in myasthenia.

Dr Leite is visiting Professor of the University of Porto, where she was also graduated in medicine and did all her medical and neurology training and worked as consultant neurologist – neuroimmunologist - for 10 years before moving to the UK in 2002. While in Portugal, and in addition to her main clinical and academic activities, Dr Leite was vice-president and general secretary of the Portuguese Neurological Society for 5 years.



## Anu Jacob

### Work Experience

August 2007–  
Present

Consultant Neurologist  
The walton Centre Foundtation Trust , (United Kingdom)  
General and MS Neurologist  
Lead Neuromyelitis Optica Service

### Education and Training

July 2006–June  
2007

Fellowship  
Mayo Clinic , (United States) NMO and MS Fellowship

### Additional Information

Expertise      Neuromyelitis optica, Transverse Myelitis  
Memberships   Association of British Neurologists  
Royal College pf Physicians London Guthy Jackson Foundation

## Ayesh Perera

Ayesh Perera graduated with a BSc and PhD from the University of Bristol, UK, after which he moved the US to undertake post-doctoral research, first at the University of Pittsburgh and then the University of Texas M.D. Anderson Cancer Center. He then made the switch to pharmaceutical research working for a number of small biotech companies in California, before returning to the UK. Since his return four years ago he has worked for Chugai Pharma Europe where he currently is the Associate Director for Research Alliances and serves as the European Project Leader for the anti-IL6 receptor SA237 for NMO.

## Dirk Mentzer

- Chair of Paediatric Committee since 2013
- Member of the Drug Safety Commission of the German Society of Paediatrics since 3/2006
- Member of ISOP (international society of Pharmacovigilance)
- Member of the EMA Paediatric Committee since 07/ 2007
- Paul-Ehrlich-Institut, (Germany)

The duties responsibilities as Head of Pharmacovigilance at the German national agency for Vaccine and biomedicinal products (Paul-Ehrlich-Institut) commenced in 2004. Based on the specialised responsibility in Pharmacovigilance and the paediatric medical education the CHMP has supported the appointment as a co-opted member for paediatric pharmacovigilance into the Pharmacovigilance Working Party at EMA from 2006 – 2012.

Medical education was performed at University hospital in Frankfurt am Main, Germany. Paediatric

Specialist training commenced 1991 at University Children hospital in Frankfurt am Main until 1997 with special interest in paediatric Immunology, Haematology and HIV-infected children. Finalising Paediatric speciality training followed by an appointment as a Consultant in General Paediatric leading the accident/emergency admission unit at University Children hospital in Frankfurt am Main.

For full CV please see EMA Homepage > Committees > PDCO > Members

## Cheryl Hemingway



Dr Cheryl Hemingway has been a Consultant Paediatric Neurologist for 15 years. She has been a full time Neurology Consultant at Great Ormond Street Hospital since 2005.

**Specialisms** Dr Hemingway's PhD from Imperial College London explored the patient response to brain inflammation and infection, and she has used the expertise gained from this to provide specialised clinical care to children with rare neuro-inflammatory disorders, as well as also providing care for children with many other neurological problems.

**Qualifications and training** Dr Hemingway has worked and trained in neurology at Red Cross Children's Hospital in South Africa and The Johns Hopkins in the USA and in the UK.

**Research interests** Dr Hemingway has established the Demyelinating Disease service at Great Ormond Street Hospital, and now runs one of the largest clinics in the country for children with multiple sclerosis and other rare demyelinating disorders. She has an ongoing research role in this area and is an active member of both the UK and the International Paediatric MS Study Group. She is an Honorary Clinical Lecturer at both Imperial College London and the UCL Institute of Child Health.

## Josephine Glover

Independent Pharmaceutical Physician

Dr Josephine Glover has an MA in Psychology and Physiology from Oxford University and a medical qualification (MBBS) from the University of London. She is a Member of the Faculty of Pharmaceutical Physicians of the Royal College of Physicians of London (MFPM) and has been working as a pharmaceutical physician for more than 25 years, specialising in clinical research, regulatory issues and drug safety. Over the years she has worked in many therapeutic areas but her experience has been mostly in oncology and inflammatory diseases. Much of her recent work, including her experience within the MHRA, has involved products of biotechnology. Jo started her pharmaceutical career at Smith, Kline and French, becoming Head of the UK Cardiovascular Group of the merged SmithKline Beecham. She went on to set up and run the European clinical trials operation for Isis Pharmaceuticals Inc as Vice President, International Drug Development. For the last 13 years Jo has been working as an independent consultant for a wide variety of clients and as a member of Data Safety Monitoring Boards for a number of large clinical trial programmes.

## Robert Hemmings



Rob Hemmings is a professionally qualified medical statistician. He has been with the Medicines and Healthcare products Regulatory Agency (previously Medicines Control Agency) for more than 13 years and heads the group of medical statisticians. Much of Rob's time is spent educating medical colleagues in the importance and artistry of clinical trial statistics; their use in proof and in obfuscation. Rob currently holds the following positions within the European drug regulatory system:

- CHMP member: CHMP is the body responsible for preparing the opinions of the European Medicines Agency on all questions concerning medicinal products for human use. Rob is one of the 32 voting members of this key European committee.
- Chair of the CHMP's Scientific Advice Working Party (SAWP) with responsibility for preparing advice to the pharmaceutical industry on the appropriate tests and trials to conduct in the development of a medicine for marketing authorisation. This group includes approximately 50 regulatory scientists from across the European regulatory network and handles approximately 400 scientific advice / protocol assistance and qualification of biomarker procedures each year.
- Rob is also a member of CHMP's Biostatistics working party with responsibility for giving advice on matters relating to clinical trial methodology across the EU regulatory network.

## Jane Moseley



Scientific Officer in the European Medicines Agency (EMA)

Scientific Advice Office, Product Development and Scientific Support Department

Human Medicines Research and Development Support Division

Part of Team responsible for administration of Scientific Advice procedures at the EMA since 2009 including procedures involving orphan medicines, small and medium enterprises, advanced therapies, paediatric scientific advice, and parallel advice involving HTAs.

Professional background in ophthalmology, epidemiology and pharmaceutical regulation:

Completed medical degree Trinity College, Dublin, Fellowship of the Royal college of Ophthalmologists (FRCOphth) and Fellowship of the Royal college of Surgeons Ireland in ophthalmology (FRCSI Ophth), and MSc in Epidemiology at the London School of Hygiene and Tropical Medicine (LSHTM).

Previously medical assessor at the Medicines and Healthcare products Regulatory Agency (MHRA) 1999-2009 working in pharmacovigilance, pharmacoepidemiology, clinical trials, and licensing procedures.

Member of the Faculty of Pharmaceutical Medicine UK, and the UK General Medical Council (GMC) registered Physician with a Licence to Practise.