

Workshop on

The Benefits of a Simplified and Coherent Clinical Trials Framework in Europe

1 December 2011 – 13:30-16:00

European Parliament, room JAN 6Q1

Hosted by MEP Prof. Philippe Juvin and organised by EuropaBio

Speakers Biography

Prof. Philippe Juvin, MD PhD

Member of the European Parliament

Philippe Juvin was born in 1964. He was first elected as Member of the European Parliament for the Ile-de-France region in 2009.

He is a licensed physician and Professor of Medicine in Paris. He also heads the Emergency department of the European Research Hospital Georges Pompidou in Paris. He is a member of the National Committee on Alzheimer's and one of the leading experts of the French presidential majority on health, disabilities and dependence. On top of his medical and parliamentary duties, Philippe Juvin has also been Mayor of La Garenne-Colombes since 2001. He is the UMP National Secretary in charge of professional federations.

From 2004 to 2009, Philippe Juvin was Vice-President of the General Council of the Hauts-de-Seine Department in France. He is a reserved officer in the French Army's Medical Corp and in 2008, served as a medical officer with NATO in Afghanistan.

Nessa Childers

Member of the European Parliament

Nessa Childers is an Irish Labour Party politician and Member of the European Parliament (MEP) for the Ireland East constituency. Previously Nessa was a councillor for the Blackrock area of South Dublin 2004–2008.

A member of the European Parliament's Committee on the Environment, Public Health and Food Safety, Nessa is also member the delegation for relations with Japan and substitute member of the Committee on Culture and Education.

Nessa's policy Priorities in the European Parliament include:

- Public health, promoting positive mental health and working on an EU-wide basis to tackle health challenges from Alzheimer's and dementia to cancer.
- Greater transparency in parliamentary and political decision-making, and is working and campaigning for greater regulation for lobbyists both in Dublin and Brussels.
- Tackling climate change while protecting wildlife and our built and natural heritage

Nessa Childers has an Arts and Psychology degree from Trinity College, Dublin and a postgraduate diploma in psychology from University College Dublin. Prior to her election to the European Parliament in 2009 Nessa worked as a psychoanalyst for over twenty years. Her practice was established in 1986 with her former husband Ross Skelton. In 1993, along with colleagues, Nessa established the M. Sc. course in Psychoanalytic Psychotherapy in Trinity College Dublin. As well as lecturing and teaching, she was course Director between the years 2001 to 2006.

Dr. Antonia Parvanova, MD
Member of the European Parliament

Antonia Parvanova Dr (1962), Bulgarian, Paediatrician and Public Health policy expert, is currently Member of the European Parliament, Vice-President of the Alliance of the Liberals and Democrats for Europe (ALDE), and seats as a full Member of the Committee on the Environment, Public Health and Food Safety. She is a substitute Member of the Committee on the Internal Market and Consumer Protection, and is also ALDE group coordinator for the Committee on Women's Rights and Gender Equality.

Following her career as a clinician and public health researcher in Bulgaria and in the UK, Dr Parvanova started her political career when elected Member of the Bulgarian Parliament in 2001. There, she was Vice-Chairperson of the Committee on Public Health and worked actively on public health and healthcare legislations at national level.

In the European Parliament, she initiated several public health policy actions, notably the campaign on patients' rights in Europe in 2007. She now continues being actively involved in public health and pharmaceutical dossiers currently being discussed at European level, as well as in other related areas such as food, environment and consumers policies.

Dr. Patricia Brunko
Head of Unit D3 – Pharmaceuticals, DG SANCO, European Commission

Patricia Brunko studied chemistry and molecular biology at the University of Brussels. Following her Ph.D., she first pursued a career in research and teaching. She then entered the European Commission, where she has worked in four different areas: Pharmaceuticals, Control of Industrial Chemicals, Food Safety and Public Health. She currently holds the position of Head of the Unit "Pharmaceuticals" in the Directorate-General for Health and Consumers.

Dr. Detlef Niese**Head of Global Development External Affairs, Novartis Pharma AG, and Vice-Chair for Science, EuropaBio Healthcare Council**

Detlef Niese is head of External Affairs in Global Development at Novartis Pharma A.G responsible for policy and ethical issues concerning drug development. He is a licensed pharmacist and physician with board certification in internal medicine and specialisation in Clinical Immunology.

From 1974-1978 he worked as a research fellow in immunogenetics with Prof. C. Rittner of the DFG Research focus "MHC linkage group on Chromosome 6". In 1980 he obtained a research based doctoral degree in immunogenetics from the faculty of Medicine in Bonn, Germany. From 1979-1992 he worked at the Department of Internal Medicine, University of Bonn. Following board certification and habilitation he was responsible for Clinical Immunology (inpatient, outpatient and labs) and Clinical Pathology.

Following 18 years in research and medical practice at the university of Bonn, Dr. Niese joined Clinical Research and Development of Sandoz AG in 1992 which later became Novartis AG. He held positions of increasing responsibility in Clinical R&D working on programs in the areas of organ transplantation, xenotransplantation, clinical immunology, infectious diseases, dermatology and tissue engineering as well as programs in tropical disorders including malaria.

Since 2003 he is responsible for External Affairs in Clinical R&D and since 2008 in Global Development. Dr. Niese is member of the Faculty of Medicine of the University of Bonn, Germany, teaching Internal Medicine and Clinical Immunology. He has also a teaching assignment at the faculty of medicine, University of Basel, Switzerland and is a member of the Executive Board of the Pharma Center at the university of Basel.

Dr. Niese was a member of the European STRATA group on Legal, Societal and Ethical Issues of Genetic Testing 2003-2004. He is a member of the Board of Management and Vice Chair for Science at the Healthcare Council of EuropaBio, the European Biotech Association, of the Board of Directors of the European Platform for Patient Associations, Science and Industry and Secretary of the Novartis Foundation for Biological and Medical Research.

Flaminia Macchia**EU Public Affairs Director, EURORDIS**

Flaminia Macchia joined EURORDIS in 2004 as European Public Affairs Officer after having already worked for EURORDIS as a consultant.

She now heads the European Public Affairs team in Brussels where her role is to increase EURORDIS influence on EU policies and programmes by collecting and analysing policy information, cultivating and expanding contacts important to EURORDIS, and helping to diversify financial resources.

Before joining EURORDIS, Flaminia worked for over ten years in EU affairs at the European Commission (Euro-Mediterranean partnership), in the European Parliament as an assistant to an Italian MEP, and in the health team of a leading EU policy consultancy firm in Brussels.

As a patient with the rare disease Colitis Ulcerosa, Flaminia has been active in the European rare disease community, more specifically in public health issues.

Flaminia holds an honours degree from the Université Libre de Bruxelles in Political Science with a specialisation in Middle Eastern Politics, and a Master of Arts in International Relations with a specialisation in EU Institutions and Middle Eastern Politics from the London School of Economics.

An Italian national, Flaminia speaks Italian, English, French and Spanish.

Dr. Christiane Abouzeid

Head of Regulatory Affairs, BioIndustry Association (BIA), and Topic Leader, EuropaBio Clinical Trials Topic Group

Christiane has been with the BIA since May 2004. She is a lawyer responsible for regulatory issues concerning the research and development of novel technology products and has been involved in influencing legislative and policy developments affecting the life sciences industry in the EU.

Christiane is the Clinical Trials Topic Leader for EuropaBio, the European Association for Bioindustries.

Previously, Christiane was part of the Biosciences Group at Eversheds, joining shortly after qualification at Llewellyn Zeitman (now Shook Hardy & Bacon LLP). She worked at the European Commission for one year.

Prior to her legal career, Christiane was a research scientist at University College London and Imperial College School of Medicine for over 12 years. She holds a PhD in microbiology and biochemistry from the University of Louvain (Belgium).

Prof. Hubert E. Blum

President, Federation of European Academies of Medicine (FEAM) and Dean of Medicine, University of Freiburg

Hubert E. Blum is President of FEAM, Chairman of Scientific Advisory Board of European Academy of Sciences and Fellow of German National Academy of Sciences Leopoldina.

He is Dean of Medicine at the University of Freiburg, Chairman of and Professor of Medicine in the Department of Medicine II (Hepatology, Gastroenterology, Endocrinology, Infectious Diseases) at the University Hospital of Freiburg. He was the Director of Medicine at the University Hospital of Zurich. Dr. Blum holds a doctorate from the University of Freiburg. He did his postgraduate training in biochemistry and molecular virology at the University of Washington in Seattle, the University of California in San Francisco and the Massachusetts General Hospital, Harvard Medical School in Boston.

He serves as Member of Scientific Committee of the Fritz Thyssen Foundation in Cologne, Advisory Board Member of Dr. Norbert-Henning-Foundation at University of Erlangen and Scientific Advisory Board Member of Dr. Wilhelm-Eitel-Foundation at University of Freiburg.

He is Editor of *Der Gastroenterologe* and 'Prinzip & Perspektive', *Deutsche Medizinische Wochenschrift*; Editorial Board Member of *Cancer Molecular Biology*, *BMC Gastroenterology*, *World Journal of Gastroenterology*, *Journal of Cellular and Molecular Biology*, *Journal of Global Hepatitis*, *Viral Hepatitis Reviews*, *Elazahar Assiut Medical Journal* and *Frontiers of Medicine in China*; and International Board Member of *Chinese Hepatology*, *Minerva Medica* and *Chinese-German Journal of Clinical Oncology*.

Dr. Hartmut Krafft**Co-Chair, EU Heads of Medicines Agencies' Clinical Trials Facilitation Group, Coordinator of the Voluntary Harmonisation Procedures and Head of the Clinical Trials Section, Paul-Ehrlich Institute, Germany**

Dr. Hartmut Krafft is Head of the Clinical Trials Unit at the Paul-Ehrlich-Institut in Langen, Germany. He is also Co-chair of the EU Heads of Medicines Agencies' Clinical Trials Facilitation Group and Coordinator of the Voluntary Harmonisation Procedure implemented by the CTFG.

Prior to becoming Head of the Clinical Trials Unit at the Paul-Ehrlich-Institut, Dr. Krafft was involved in the assessment of antibodies, batch-release testing and regulatory affairs at the Institute, which is the Federal Institute for Vaccines and Biomedicines in Germany. Alongside his current role, he is a member of several working parties involved in clinical trials e.g. the ad hoc group on the CTD.

Dr. Krafft gained his Master degree and PhD thesis at the German Cancer Research Center Heidelberg, Department of Cell Biology and Immunology. As Post-Doc, he worked at the German Cancer Research Centre and the European Molecular Biology Laboratory in Heidelberg, as well as for the Institute of Pathology at the University Hospital in Regensburg.

Prof. Olivier Chassany**Chairman of a French Ethics Committee, Paris, and Medical Head of the Department of Clinical Research and Development, AP-HP (Assistance Publique – Hôpitaux de Paris)**

Professor Olivier Chassany, MD, PhD, is a specialist physician in Gastroenterology by training. He teaches therapeutics, methodology and management of clinical research, ethics of clinical research and patient-reported outcomes at University Diderot - Paris 7.

He has had clinician responsibilities for over 17 years in gastroenterology and internal medicine.

Since 2001, he holds the medical head of the Department of clinical research and development of Assistance Publique - Hôpitaux de Paris (<http://rechercheclinique.aphp.fr/>). This department is an institutional sponsor (investigator-based clinical trials) and currently promotes 800 interventional and observational studies ranging from physiopathology studies to gene therapy clinical trials.

He holds the chair of a Parisian Ethics Committee (agreed as US Institutional Review Board). He is member and reviewer of several committees of the French Drug Agency (AFSSAPS) and is a clinical expert for EMA (European Medicines Agency).

He is the co-author of the EMA Reflection Paper on Health-Related Quality of Life. He has developed several Patient-Reported Outcomes questionnaires, among them the Functional Digestive Disorders Quality of Life Questionnaire (FDDQL), or the PROQOL-HIV, a new specific quality of life questionnaire for people living with HIV. He has recently structured his research activities with the creation of a methodological research unit on clinical endpoints. He is Associate Editor of the "Health Outcomes Research in Medicine" journal (Elsevier).

Kaisa Immonen-Charalambous
Senior Policy Adviser, European Patient's Forum (EPF)

Kaisa Immonen-Charalambous is Senior Policy Adviser at the European Patients' Forum. A Finnish national, she has an MA in International Relations and Conflict Resolution. She is responsible for EPF's policy and advocacy work at EU level; monitoring health-related policy developments, liaising with the EU institutions and stakeholder organisations, advising on policy issues, and developing EPF's campaign and advocacy strategies. She has previously worked in the private and non-profit sectors focusing on European health policy, patient advocacy and communications.

Prof. Dermot Kelleher
Vice-President elect of FEAM and Head of School of Medicine and Vice Provost for Medical Affairs, Trinity College Dublin

Prof Dermot Kelleher MD, FRCP, FRCPI, F Med Sci, AGAF, graduated in Medicine from TCD in 1978 and completed specialist training in Gastroenterology in Dublin. He subsequently received a Fogarty Scholarship for a research fellowship at University of California San Diego. In 1989 he was appointed as a Wellcome Senior Fellow in Clinical Science at Trinity College Dublin and was subsequently appointed as Professor of Clinical Medicine in 2001 and Head of School of Medicine and Vice-Provost for Medical Affairs in 2006.

Professor Kelleher's research has focused on the cell biology of immune responses both in terms of basic lymphocyte function and in relationship to mucosal immunology. His research has been focused on the immune response to many of the leading causes of infectious disease worldwide. He is the author of over 200 publications including papers in journals such as Nature Immunology, Nature Methods, Nature Genetics, Journal of Experimental Medicine, Gastroenterology, Hepatology, Journal of Biological Chemistry, PLOS Pathogen and Journal of Immunology. He is also the author of 14 patents.

Prof Kelleher has been successful in obtaining funding from NIH, Wellcome Trust, European Union, Programme for Research in Third Level Institutions (Higher Education Authority), Health Research Board and Enterprise Ireland. Prof Kelleher is a founder of the Dublin Molecular Medicine Centre, now Molecular Medicine Ireland. Prof Kelleher obtained funding for the construction of the Institute of Molecular Medicine, a TCD facility at St James' Hospital. More recently, he has been successful in obtaining funding for a Wellcome Trust HRB funded Clinical Research Centre at St James's Hospital, a 22m€ grant. Prof Kelleher was also the PI for the development of a 4 year PhD programme in molecular medicine funded by the Health Research Board.

Prof Kelleher is a founding member of Opsona Therapeutics, a campus company at Trinity College Dublin based on development of therapeutic technologies founded on innate immunity. He is a director of ICON plc and of Cellix, a nanofluidics company and of Allegro Deerac, now merged with Labcyte.

Prof Kelleher has served as a member of the Board of the Health Research Board Ireland, the European Medical Research Council, the Wellcome Trust Clinical Interest Group and the National Institute of Health Research Review Panel. He is currently Chairman of the Eurolife Consortium of European Medical Schools. He also serves on several National and International Bodies in the Health sector.

Charmian Wells**Vice-President of Regulatory Affairs, Circassia Limited, and member of the EuropaBio Clinical Trials Topic Group**

A biochemist, with 19 years of experience in regulatory affairs and strategies for the development of biologics and small molecules, Charmian has established and led industry functions and teams in the lean organisations of SMEs and the global matrix structures of Pharma.

Charmian's career experience includes that at Sequus Pharmaceuticals Inc./Alza Corporation obtaining clinical trial authorisations to enable a phase III clinical programme to extend the indication for pegylated liposomal doxorubicin hydrochloride and market authorisations for Amphocil®/Amphotec®. Whilst at Amgen, further hands on experience of the development of novel products based on advances in recombinant DNA and molecular biology was gained in the market authorisation of Kineret® and Neulasta®, also leading the Company's first European Orphan Drug Designation application. Building on her knowledge and experience in global regulatory affairs, Charmian took on the role of Head of Regulatory Affairs & Quality Systems functions at Arakis/Sosei R & D Ltd and at PanGenetics BV. Now at Circassia Limited, a specialty biopharmaceutical company focused on developing immunotherapies including a new class of T cell vaccines, several of its products are in mid- to late- stage development having successfully completed a number of Phase II clinical studies.

Charmian is actively involved in regulatory policy and advocacy acting on the BIA Regulatory Affairs Advisory Committee and the EuropaBio Clinical Trials Topic Group.
