

Meeting Programme

A Roundtable Event Hosted by Nessa Childers MEP
'Data Protection Regulation: Keeping Health Research Alive in the EU'

European Parliament, Brussels - ROOM ASP 5 F 385
Tuesday 17th September 2013 from 16:00 - 17:30
(followed by cocktail reception from 17:30 - 18:30)

Meeting Chairmen: *Prof. Helmut Brand, EAPM Co-Chair*
Prof. Robert Souhami, FEAM Scientific Adviser

Welcome

16:00 – 16:15

- **Nessa Childers MEP**, ENVI Committee on the Environment, Public Health and Food Safety

Keynote address:

'Data Protection Regulation – Keeping Health Research Alive in the EU'

16:15 – 17:00

- **Patients' Perspective**
Stephen McMahon, Chairman and co-founder of the Irish Patients' Association
- **Academic Perspective**
Prof. Richard Frackowiak, Science Europe - Chair of Medical Sciences Committee
- **Industry Perspective**
Dr. Greg Rossi, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- **Ethical and Societal Perspective**
Prof. Jean-Marie Maloteaux, FEAM, Académie royale de Médecine de Belgique

Discussion with the audience

17:00 – 17:20

- **Moderated by**
 - *Prof. Helmut Brand, EAPM President*
 - *Prof. Robert Souhami, FEAM Scientific Adviser*

Conclusions

17:20 – 17:30

- **Nessa Childers MEP**

Cocktail Reception

17:30 – 18.30

Stephen McMahon, Chairman and co-founder of the Irish Patients' Association (IPA)



Stephen McMahon was educated at Blackrock College and Trinity College in Dublin, where he obtained a Diploma in advanced Systems Analysis. He has wide business experience having worked for 30 years for a large multinational oil company.

McMahon is Chairman and co-founder of the Irish Patients' Association (IPA). The IPA has pioneered patient advocacy, patient safety and healthcare quality and service user involvement since its inception. It has dealt with thousands of patients, their families and others who have shared adverse experiences of the health care system.

A trusted expert in representing the patients' interests on many media and public and institutional platforms both nationally and internationally, Stephen is a former member of the Governing Board of the International Alliance of Patients Organisations (I.A.P.O), advocating patient centered care for over 60 countries. He is also associated with many regulatory bodies and hospital bodies, working on boards and committees of organizations such as the Medical Council Ireland, currently chairs the Audit Risk and Governance committee for C.O.R.U, (Regulating Health and Social Care Professionals) , Interim board member Tallaght Hospital, Pharmaceutical Society of Ireland, Pre Hospital Emergency Care Council , H.T.A. Scientific Advisory Group H.I.Q.A. member R.C.P.I. Research Ethics committee.

He is driven by the maxim that "Change and Reform in our health care system should not be preceded by avoidable funerals and injury to patient"

Prof. Richard Frackowiak, Science Europe, CHUV Lausanne, and co-Director of Human Brain Project



Richard Frackowiak is Head of the Department of Clinical Neurosciences at the Université de Lausanne, Switzerland, co-Director of the Human Brain Project, and Chair of the Medical Sciences Committee of Science Europe.

Professor Frackowiak's interest is in human brain structure and function relationships in health and disease. Formerly Foundation Professor of Cognitive Neurology at University College London (UCL), Director of the Department of Cognitive Studies at the Ecole Normale Supérieure Paris, Wellcome Trust Principal Clinical Research Fellow, Dean-Director of the Institute of Neurology and Vice-Provost of UCL, he founded the Wellcome Department of Imaging Neuroscience (FIL) in 1994. MA and MD Cambridge, DSc London University, he holds an honorary doctorate from Liege University and professorship from UCL. He is a Fellow of the Academies of Medical Sciences of the UK, France Belgium and the Academia Europaea and a foreign associate of the Institute of Medicine USA.

Dr. Greg Rossi, EFPIA, AstraZeneca, VP Payer and Real World Evidence



Greg Rossi received his doctorate in Molecular Biology and Protein Chemistry from the University College London (UCL) in 1993. Since then he has worked in the biotechnology/pharma industry. Between 1996 and 2007 Dr Rossi was at Amgen Inc where he held a number of roles in regulatory affairs, clinical development and global product strategy. He was involved in the clinical development and registration of a number of products with responsibilities including negotiations reimbursement authorities and payers. Between 2005 and 2007 Dr Rossi was responsible for co-leading the development and commercialisation of Amgen's therapeutic oncology pipeline in phase 2 and 3 clinical development. In 2007 Dr Rossi joined Genentech Inc/Roche Pharmaceuticals where he was responsible for outcomes research, health economics and global pricing. These responsibilities included providing input into the design of phase 2, 3 and 4 studies, conducting observational research studies, development pricing policies as well as the generation of Health Technology/Reimbursement Dossiers for coverage and reimbursement submissions. Dr Rossi joined AstraZeneca in August 2011. As VP, Payer and Real World Evidence, he has global responsibility for coverage and reimbursement submissions, real world evidence (outcomes) studies and ensuring development programs address evidence requirements of payers. Dr Rossi is author over 25 clinical research manuscripts and numerous abstracts.

Prof. Jean-Marie Maloteaux, FEAM, Académie royale de Médecine de Belgique



Jean-Marie Maloteaux is neuropsychiatrist, head of the department of clinical neurology at the Brussels Saint Luc university Hospital of the Catholic University of Louvain in Belgium. He was a qualified researcher of the National Funds for Scientific research in neurochemistry both at the Catholic University of Louvain and in Janssen Pharmaceutica and got the highest scientific degree in 1991. Since 2003 he is full Professor in the department of physiology and pharmacology, and now council president of the Institute of Neuroscience at the same University. He was member of the commission for registration of medicines and is member of working groups at the Federal Agency for Medicines and Health Products (Belgium). He is member of the Commission for Reimbursement of Medicines and Chief editor of the Belgian Center for Pharmacotherapeutic Information (CBIP/BCFI). He presently chairs the Ethics Committee of his University and university Hospital. He is member of the Belgian Advisory Committee on Bioethics and Fellow of Académie royale de Médecine de Belgique.

Prof. Robert Souhami, FEAM, The UK Academy of Medical Sciences



Robert Souhami CBE FMedSci is Foreign Secretary of the UK Academy of Medical Sciences and Scientific Adviser at FEAM. He graduated from University College London. He was Physician and Senior Lecturer in Medical Oncology at University College London from 1975 to 1987 and Kathleen Ferrier Professor of Cancer Medicine at University College London from 1987 to 1997. In 1997 he became Dean of University College and Middlesex Medical School and subsequently Principal of the newly formed Royal Free and University College Medical School. He was Director of Clinical Research at Cancer Research UK from 2001 to 2005.

Prof. Helmut Brand, Co-Chair, EAPM



Helmut Brand is Jean Monnet Professor of European Public Health and head of the Department of International Health at Maastricht University, The Netherlands. He studied Medicine in Düsseldorf and Zürich and earned a Master in Community Medicine from London School of Hygiene and Tropical Medicine and London School of Economics. Prof. Brand is a specialist in Public Health Medicine. After working in several Health Authorities and Ministries of Health in Germany he was director of the Public Health Institute of North Rhine Westphalia. Since then European Integration in Health is the main topic of his work. He is president of the Association of Schools of Public Health in the European region (ASPHER) and president of the European Health Forum Gastein (EHFG). As policy advisor he serves on the European Advisory Committee on Health Research (EACHR) of WHO Europe and on the Expert Panel on "Investing in Health" for the European Commission.

Roundtable co-hosts

About the Medical Sciences Committee of Science Europe



Science Europe is an association of major European Research Funding and Research Performing Organisations, founded in October 2011 and with an office based in Brussels. Science Europe Member Organisations share a common mission: to fund and perform excellent research. Collective action and cross-border collaboration can contribute to achieving excellence in research, and Science Europe provides a platform for its members to pursue this objective and to speak with a common voice to the European institutions, national governments and other stakeholders. In its efforts to foster and strengthen the European Research Area (ERA), and in its reflections on policies, priorities and strategies, Science Europe is informed by direct representation of all scientific communities through its six Scientific Committees. The **Medical Sciences Committee of Science Europe** is co-hosting the roundtable.

Science Europe Office: Rue de la Science 14, 1040 Brussels, Belgium
<http://www.scienceeurope.org>

About EAPM



European Alliance for
Personalised Medicine

The **European Alliance for Personalised Medicine (EAPM)** brings together Europe's leading healthcare experts and patient advocates to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics. It is calling for the European Commission, the European Parliament and EU member states to help improve the regulatory environment so that patients can have early access to personalised medicine, and so that research is boosted. The EAPM is therefore calling to help encourage the introduction of personalised medicine by:

- i. Ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine
- ii. Increase research and development for personalised medicine
- iii. Improve the Education and Training of Healthcare Professionals
- iv. Acknowledging new approaches to reimbursement and HTA assessment, which are required for patient access to personalised medicine and its value to be recognized
- v. Increase awareness and understanding of personalised medicine

EAPM Office: Rue De L'aqueduc 88A, 1050 Ixelles, Brussels, Belgium

<http://euapm.eu/>

About the Wellcome Trust

wellcometrust

The **Wellcome Trust** is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

Wellcome Trust Office: Gibbs Building, 215 Euston Road, London NW1 2BE, UK

www.wellcome.ac.uk

About FEAM



FEAM

Federation of European
Academies of Medicine

Since 1993, **FEAM**'s mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe, to provide them with a platform to formulate their collective voice on matters concerning medicine, biomedical research and public health with a European dimension, and to extend to the European authorities the advisory role that they exercise in their own countries on those matters. Our vision is: (1) to underpin European biomedical policy with the best scientific advice drawn from across Europe, through the FEAM network of Academies representing over 3000 high level scientists from the whole biomedical spectrum; (2) to improve the health, safety and wealth of European citizens through research by promoting a nurturing, creative and sustainable environment for medical research and training in Europe. FEAM's strength lies in its member Academies that give it the authority to provide an EU-wide scientific opinion on the European medical science base and evidence to underpin European biomedical policy. The FEAM Academies represent the following EU Member States: Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Portugal, Romania, Spain, United Kingdom. Observers include the European Academies Science Advisory Council (EASAC – the European network of Academies of Sciences) and the InterAcademy Medical Panel (IAMP – the global network of Academies of Medicine).

FEAM Office: Palais des Académie Rue Ducale 1, B-1000 Brussels, Belgium

<http://www.feam.eu.com/>