



FEAM

Federation of European
Academies of Medicine

Palais des Académies
Rue Ducale 1
B-1000 Bruxelles
Tel: 0032 (0) 2 550 22 68
Fax: 0032 (0) 2 550 22 65
E-mail : info@feam.eu.com
Web : www.feam.eu.com

GERECHTIKAET

Ethical Review of Clinical Research

10:00 – 16:00, 17 March 2014
Albert 1st Room, Palais des Académies,
Rue Ducale 1, B-1000 Brussels



Under the patronage of the
Belgian Royal Academies of
Medicine

PROGRAMME

10:00 – 10:15: Welcome and introduction

Prof. Bernard Charpentier (Member, French National Academy of Medicine, Chair of the FEAM Working Group on Ethical Review of Clinical Research)

Head Department of Nephrology, Dialysis, Transplantation, University Hospital of Bicêtre-94275 Kremlin-Bicêtre-F; Research Unit 1014 INSERM/University Paris Sud 11; Honorary Dean, Faculty of Medicine Paris Sud 11; Past-President of the French Medical School Deans' Council

Dr. Philippe Mettens (President, Belgian Federal Science Policy Office – BELSPO)

10:15 – 11:45: Presentations

10:15 – 10:25 The new Regulation on Clinical Trials, an overview on the agreed text and on the next steps

Dr. Fabio D'Arti, Deputy Head of Unit - 'Medicinal products - quality, safety and efficacy', DG Health and Consumers, European Commission

10:25 – 10:35 The EGE position on the Clinical Trials Regulation and research ethics evaluation

Dr. Jim Dratwa, European Group of Ethics in Science and New Technologies (EGE), Bureau of European Policy Advisers (BEPA), European Commission

10:35 – 10:45 Re-engineering and integrating research ethics committees

Prof. Adam Cohen, Science Europe's Medical Sciences Committee; Director of the Centre for Human Drug Research (CHDR), The Netherlands

10:45 – 10:55 Issues for remit, composition and effectiveness of research ethics committees

Prof. David Smith, Irish Academy of Medical Sciences; Associate Professor of Health Care Ethics, Department of General Practice, Royal College of Surgeons in Ireland

10:55 – 11:05 Ethical review in paediatric – oncological clinical research

Dr. Laurence Dedeken, Deputy Head of Clinic, Department of Hemato-oncology, Queen Fabiola Children's University Hospital (HUDERF), Brussels

11:05-11:15 The perspective from a not-for profit organisation on clinical research ethics review

Anastassia Negrouk, Head of International Regulatory and Intergroup Office, Chair of EORTC IRB, European Organisation for Research and Treatment of Cancer (EORTC)

11:15-11:25 The perspective from the pharmaceutical industry on clinical research ethics review

Dr. Nick Sykes, Pfizer; Co-chair, Clinical Trials Regulation Working Group, European Federation of Pharmaceutical Industries and Associations (EFPIA)

11:25-11:35 How best can patients participate in the ethical review of clinical research?

Flaminia Macchia, Policy Director, EURORDIS Rare Diseases Europe

11:35-11:45 Embedding research ethics in Horizon 2020 research: from compliance check to ethics thinking

Dr. Isidoros Karatzas, Head of the Ethics Sector, DG Research and Innovation, European Commission

11:45 – 13:00: Roundtable and Q&A session

Chair: *Prof. Bernard Charpentier*

5-minute intervention by experts from the FEAM Working Group:

Prof. Maria Dorobantu (Romania)

Member, Romanian Academy of Medical Sciences
Professor of Cardiology and Head of the Cardiology Section, Emergency Hospital Bucharest

Prof. Diego Gracia (Spain)

Member, Spanish Royal National Academy of Medicine
Emeritus Professor of History of Medicine and Bioethics, Complutense University in Madrid

Prof. Sándor Kerpel-Fronius (Hungary)

Hungarian Academy of Sciences
Department of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest

Prof. Jean-Marie Maloteaux (Belgium)

Member, Belgian Royal Academy of Medicine (ARMB)
Head of the Department of Clinical Neurology and Chair of the Ethics Committee, Brussels Saint Luc Hospital, Catholic University of Louvain

Prof. Daniel Moura (Portugal)

Vice President, Portuguese National Academy of Medicine
Institute of Pharmacology and Therapeutics, Faculty of Medicine, University of Porto

Prof. Hans-Peter Zenner (Germany)

Member of the Presidium, German National Academy of Sciences Leopoldina
Professor and Chairman, Department of Otolaryngology, Head and Neck Surgery, University of Tübingen

Q&A session

13:00-14:00: buffet lunch

14:00-16:00: general discussion

Chair: *Prof. Bernard Charpentier*