

EFGCP Geriatric Medicines Working Party Workshop

The challenge of an ageing population
for medical research:
Is Europe ready to cope?

Residence Palace, Brussels, Belgium
19 & 20 November 2009

organised by



'where science and ethics meet'

conferences@efgcp.be - www.efgcp.be

Workshop Rationale

The dramatic increase in longevity seen since the Second World War has had a major effect on the demographics of Europe with over one-third of the population being projected to be over 65 in just two to three decades.

This will have a major impact on medical research in the European Union.

Many clinical studies focusing on efficacy and safety have age cut-offs which limit their applicability to this population, many of which suffer from extensive multiple morbidities and increasingly consume an array of drugs. First-in-man studies are often carried out in fit young male volunteers who have vastly different pharmacodynamic and kinetic characteristics from the older predominantly female population. All of which question the current approach to drug development for this growing section of the European population.

The ageing process brings its own specific pathological and disease states which can only be studied in these populations which is lobbying in its own right for a greater research effort.

The older research participant may be particularly vulnerable in a number of ways that preclude autonomy and dignity and may limit their inclusion in clinical trials and access to the benefits of medical research. The ethical issues surrounding research experimentation in this population has also only been explored superficially and to date, there has been little recognition within the ethical medical, regulatory bodies or the political fields of the extent this markedly changing demography will have on the requirements of medical research and clinical trial and drug development in particular.

The Geriatric Medicines Working Party of the European Forum for Good Clinical Practice has thus brought together experts in the fields of clinical research, ethics, philosophy, social and patient organisations along with pharmaceutical regulatory bodies to explore the issues surrounding the effect of this demographic transition on drug development and medical research.

It is hoped this conference would be of interest, offer guidance to investigate and set the agenda for funding bodies, ethics committees, the pharmaceutical industry and regulators alike. We aim to facilitate and promulgate high quality ethical clinical research and drug development for this increasingly important population across the whole of the European Union.

Programme Committee

Michael Bone	Consultant Physician, EFGCP, United Kingdom
Laurence Hugonot-Diener	Broca Hospital, France
Jean-Marc Husson	Geriatric Medicines Working Party, EFGCP, Eudipharm, France
Marianne Maman	Novartis Pharma, Switzerland
Anthea Tinker	King's College London, Institute of Gerontology, United Kingdom
Jean-Marie Vetel	Le Mans Hospital, France
Florian von Raison	Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland

Faculty

Joël Ankri	Université de Versailles St-Quentin, France
Jean-Pierre Baeyens	European Union Geriatric Medicine Society (EUGMS), Belgium
Michael Bone	Consultant Physician, EFGCP, United Kingdom
Kristina Dunder	Medical Products Agency (MPA), Sweden
Fausto Felli	Italian Institute for Quality of Life, Italy

EFGCP Geriatric Medicines Working Party Workshop
*"The challenge of an ageing population for medical research:
Is Europe ready to cope?"*
Residence Palace, Brussels, Belgium, 19 & 20 November 2009

François Hirsch	INSERM, France
Laurence Hugonot-Diener	Broca Hospital, France
Jean-Marc Husson	Geriatric Medicines Working Party, EFGCP, Eudipharma, France
Beatrice Lucaroni	DG Research European Commission
Marianne Maman	Novartis Pharma, Switzerland
Anette Hylen Ranhoff	Kavli Research Centre for Ageing and Dementia, Diacon Hospital, Norway
Solange Rohou	AstraZeneca, France
Richard Rowson	Ethics Committee, University of Lincoln, United Kingdom
Cees Smit	Dutch Genetic Alliance (VSOP), The Netherlands
Anthea Tinker	King's College London, Institute of Gerontology, United Kingdom
Jean-Marie Vetel	Le Mans Hospital, France
Florian von Raison	Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland

Workshop Language

The language of the workshop will be English.

Workshop Venue

'Residence Palace'
Rue de la Loi 155, B-1040 Brussels
Tel.: +32.2.235 21 11
Fax: +32.2.235 21 10
Website: www.residencepalace.be
Nearest Metro Station: Schuman

For further information

Contact the EFGCP Team at: conferences@efgcp.be or tel: +32 2 732 87 83
Visit the EFGCP Website: www.efgcp.be

Agenda

Thursday, 19 November 2009

10.00 Registration & Welcome Coffee

Plenary Lectures

Chairpersons *Jean-Marc Husson, Geriatric Medicines Working Party, EFGCP, Eudipharm, France*
Michael Bone, Consultant Physician, EFGCP, United Kingdom

- 10.30 Welcome by the EFGCP Geriatric Medicines Working Party
Jean-Marc Husson, Geriatric Medicines Working Party, EFGCP, Eudipharm, France
- 10.45 7th Framework Programme Health Theme: Human development and ageing research
Beatrice Lucaroni, DG Research, European Commission
- 11.15 The EMEA and the Older Person
Jean-Pierre Baeyens, European Union Geriatric Medicine Society (EUGMS), Belgium
- 12.00 Epidemiology and older people in the EU
Joël Ankri, Université de Versailles St-Quentin, France
- 12.30 Discussion
- 13.00 Lunch

Plenary Lectures

Chairpersons *Jean-Marie Vetel, Le Mans Hospital, France*
Marianne Maman, Novartis Pharma, Switzerland

- 14.00 Medical research and potential abuse of older people
Michael Bone, Consultant Physician, EFGCP, United Kingdom
- 14.30 Some challenges in undertaking longitudinal research with older people
Anthea Tinker, King's College London, Institute of Gerontology, United Kingdom
- 15.00 Discussion
- 15.30 Coffee break

Parallel Workshops

- 15.50 **Workshop 1:** Informed consent for older people in medical research. How to improve the understanding and communication
Decision-making capacity measurement. The importance and use in medical research
Chair: *Michael Bone, Consultant Physician, EFGCP, United Kingdom*
Facilitator: *Laurence Hugonot-Diener, Broca Hospital, France*
Rapporteur: *Marianne Maman, Novartis Pharma, Switzerland*

EFGCP Geriatric Medicines Working Party Workshop
"The challenge of an ageing population for medical research:
Is Europe ready to cope?"
Residence Palace, Brussels, Belgium, 19 & 20 November 2009

Workshop 2: Clinical studies including older people. How to improve recruitment and retention
Patients advocacy groups: What are the expectations and visions toward medical
research in older people?
Chair: *Jean-Pierre Baeyens*, *European Union Geriatric Medicine Society (EUGMS)*,
Belgium
Facilitator: *to be confirmed*
Rapporteur: *Cees Smit*, *Dutch Genetic Alliance (VSOP)*, *The Netherlands*

17.30

End of day 1

Friday, 20 November 2009

Plenary Session

Chairpersons *Laurence Hugonot-Diener, Broca Hospital, France*
Florian von Raison, Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland

- 9.00 Reports from the workshops and discussion
- 10.00 Forum Discussion on Ethical considerations proposal for older people in medical research. What can we learn from the ethical consideration for children recently published by EMEA
Panelists: *Jean-Marie Vetel, Le Mans Hospital, France*
François Hirsch, INSERM, France
- 11.00 Coffee break

Plenary Lectures

Chairpersons *Laurence Hugonot-Diener, Broca Hospital, France*
Florian von Raison, Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland

- 11.20 General aspects of medical research and older people from a philosophic point of view
Richard Rowson, Ethics Committee, University of Lincoln, United Kingdom
- 11.50 How to run medical research with older people with delirium: example of patients with hip fracture
Anette Høyen Ranhoff, Kavli Research Centre for Ageing and Dementia, Diacon Hospital, Norway
- 12.20 Lunch

Plenary Lectures

Chairpersons *Anthea Tinker, King's College London, Institute of Gerontology, United Kingdom*
Co-Chairperson (to be confirmed)

- 13.20 Proposed changes in E7 relevant to safety reporting for the elderly: the Regulatory Authorities Perspective
Kristina Dunder, Medical Products Agency (MPA), Sweden
- 13.50 Revision of the ICH E7 guideline (Studies in Support of Special Populations: Geriatrics): the Industry Perspective
Solange Rohou, AstraZeneca, France
- 14.20 Health economic outcomes for older people in Europe: What are the winning strategies for countries and Europe to prepare for the future?
Fausto Felli, Italian Institute for Quality of Life, Italy
- 15.00 Coffee break
- 15.20 Open Forum Discussion & Wrap-up
Florian von Raison, Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland
- 16.00 Closing remarks
Jean-Marc Husson, Geriatric Medicines Working Party, EFGCP, Eudipharma, France
- 16.15 End of the meeting