

EFGCP Geriatric Medicines Working Party Workshop

The challenge of an ageing population
for medical research: 1/3 of the EU population will be
more than 60 years of age in 50 years time

Residence Palace, Brussels, Belgium
19 & 20 November 2009

organised by



'where science and ethics meet'

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Workshop Rationale

There has been a dynamic increase in the size of the older population in Western Europe over the last few decades which is projected to reach a huge proportion with over "one third" of the European population being over 65 by the mid century. This rise in the share of the older population will have a major impact on medical research within the European Union, as well as in other regions of the world. Many clinical studies focused on efficacy have traditionally had age cut-offs thus limiting their applicability to these people. Many older patients suffer multiple morbidities which also limit the generalisation of many clinical trial results with their narrow inclusion and extensive exclusion criteria. First-in-man studies are very often carried out in young fit male volunteers who have different pharmaco-kinetic and -dynamic characteristics from the older, predominantly female population, often with polypharmacy; all of these elements may question the current approach to drug development for this growing population.

In addition, the aging process produces its own specific pathological states and diseases which can only be studied in these populations. The older participant may also be particularly vulnerable in a number of ways which may preclude autonomy and dignity thus limiting inclusion in clinical trials and access to the benefits of medical research. The lack of research data in this population has been of increasing public concern.

There has, to date, been little recognition either within medical, regulatory bodies or political fields of the extent this markedly changing demography will have on medical research in general and clinical trials in particular in the twenty-first century.

More research is needed to enhance their quality of life and to maintain their independence as long as possible.

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, patient organisations and 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 will be of interest, offer guidance to investigators and set the agenda for funding bodies, ethics committees, the pharmaceutical industry and regulators alike, in order 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

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|-------------------------|---|
| Michael Bone | Association of Research Ethics Committees (AREC), 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 (invited) |
| Florian von Raison | Geriatric Medicines Working Party, EFGCP, Merck-Serono, Switzerland |

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*"The challenge of an ageing population for medical research:
1/3 of the EU population will be more than 60 years of age in 50 years time"*
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Faculty

| | |
|-------------------------|---|
| Joël Ankri | Université de Versailles St-Quentin, France |
| Michael Bone | Association of Research Ethics Committees (AREC), United Kingdom |
| Kristina Dunder | Medical Products Agency (MPA), Sweden |
| Fausto Felli | Italian Institute for Quality of Life, Italy |
| Representative | INSERM, France (to be confirmed) |
| Laurence Hugonot-Diener | Broca Hospital, France |
| Jean-Marc Husson | Geriatric Medicines Working Party, EFGCP, Eudipharm, France |
| Marianne Maman | Novartis Pharma, Switzerland |
| Member | European Parliament (invited) |
| Rod Mitchell | European Federation of Crohn and Ulcerative Colitis Associations (EFCCA), United Kingdom |
| François Piette | Ivry Hospital, France |
| Anette Hylen Ranhoff | Kavli Research Centre for Ageing and Dementia, Diacon Hospital, Norway |
| Representative | European Commission (invited) |
| 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

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, Association of Research Ethics Committees (AREC), United Kingdom

10.30 Welcome by the EFGCP Geriatric Medicines Working Party
Jean-Marc Husson, Geriatric Medicines Working Party, EFGCP, Eudipharm, France

Introduction
Representative, European Commission (invited)

10.45 Epidemiology and older people in the EU
Joël Ankri, Université de Versailles St-Quentin, France

11.15 Introduction on the French Alzheimer Plan
Speaker invited

12.00 Participation of older people in Clinical Trials
Speaker invited

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, Association of Research Ethics Committees (AREC), 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
Chair: *Michael Bone, Association of Research Ethics Committees (AREC), United Kingdom*
Rapporteur: *Marianne Maman, Novartis Pharma, Switzerland*
- Workshop 2:** Decision-making capacity measurement. The importance and use in medical research
Chair: *François Piette, Ivry Hospital, France*
Rapporteur: *Laurence Hugonot-Diener, Broca Hospital, France*
- Workshop 3:** Clinical studies including older people. How to improve recruitment and retention
Chair: *(invited)*
Rapporteur: *Richard Rowson, Ethics Committee, University of Lincoln, United Kingdom*
- Workshop 4:** Patients advocacy groups: What are the expectations and visions toward medical research in older people?
Chair: *Rod Mitchell, European Federation of Crohn and Ulcerative Colitis Associations (EFCCA), United Kingdom*
Rapporteur: *Cees Smit, Dutch Genetic Alliance (VSOP), The Netherlands*
- Workshop 5:** Ethical considerations proposal for older people in medical research. What can we learn from the ethical consideration for children recently published by EMEA?
Chair: *Jean-Marie Vetel, Le Mans Hospital, France*
Rapporteur: *Representative, INSERM, France (to be confirmed)*
- 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

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 Hysten Ranhoff, Kavli Research Centre for Ageing and Dementia, Diacon Hospital, Norway

12.20 Lunch

Plenary Lectures

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
Speaker invited

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

16.15 End of the meeting