EFGCP-EUCROF Joint Workshop on

Ethical Challenges in Clinical Research at Both Ends of Life

Common Lessons to be learnt from Paediatric & Geriatric Clinical Development

Brussels, Belgium
27 & 28 April 2010

organised by the

European Forum for Good Clinical Practice
&
European CRO Federation

www.efgcp.be – www.eucrof.eu
Workshop Rationale

Medical research and drug development are focused typically on an adult population of patients frequently excluding, at one end of the age spectrum, children and, at the other, the elderly and frail. Reasons for these exclusions are multiple and are not the same for both populations, but typical hurdles are shared as e.g. ethical concerns about informed consent, the need for specific formulations, specific adaptations of protocol procedures etc.

Therefore these vulnerable populations are today unrepresented in research and drug development. Once a drug is on the market and used, clinicians, patients and caregivers have to base their treatment decisions on empiric data and dose assumptions and not on scientific valid data.

This lack of data was already identified in the past, but specifically only for children. Thus drug development regulatory bodies, academia, researchers and patients' advocacy groups have recently agreed on improved and clear guidelines for research involving children. Much to be welcomed is the recently implemented, and in force in Europe since 2008, Paediatric Investigation Plan (PIP) for all new drugs in development.

At the other end of life, for the older and frail people, a lot of effort has still to be done as existing international recommendations and regulations are under review and the next steps to define what they will yield and how they will improve the situation are under discussion.

The European Forum for Good Clinical Practice (EFGCP) and The European CRO Federation (EUCROF) have thus brought together experts from both fields, experts in clinical research, ethics, social, patient organisations and pharmaceutical regulatory bodies to explore the shared ethical issues and to learn lessons from each other.

The objective of this workshop is to share concerns, to detect possible synergies and to learn from each other in order to improve and to facilitate and promulgate high quality ethical clinical research and drug development for these important populations across the whole of the European Union.

Programme Committee

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Faculty

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Ethical Challenges in Clinical Research at both Ends of Life
Brussels, Belgium, 27 & 28 April 2010
(Preliminary Programme, 24 February 2010 v5)

Peter Crome
PREDICT Project, University of Keele, United Kingdom

Hugh Davies
National Research Ethics Service (NRES), United Kingdom

Martine Dehlinger-Kremer
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François Hirsch
INSERM, France

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Ingrid Klingmann
Chairman of the Board, EFGCP & Pharmaplex, Belgium

Anna Jurczynska
Paediatric Working Group, EUCROF & SERMES, Spain

Petra Knupfer
Baden-Württemberg Ethics Committee, Germany

Soeren Rasmussen
Pfizer, USA (invited)

Agnès Saint-Raymond
Human Medicines Special Areas, European Medicines Agency

Helen Sammons
University of Nottingham, United Kingdom

Juergen Schaefer
Paediatric Working Group, EUCROF & Conreso, Germany

Philippa Smit-Marshall
Paediatric Working Group, EUCROF & PharmaNet, The Netherlands

Florian von Raison
Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland

Frank Wells
Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom

Klaus Rose
Children’s Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany

Workshop Language

The language of the Conference will be English.
Agenda

Tuesday, 27 April 2010

17:15 Registration

18:00 Welcome and Introduction to the Workshop
Ingrid Klingmann, Chairman of the Board, EFGCP & Pharmaplex, Belgium
Martine Dehlinger-Kremer, Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany

18:15 Key Note Introductions

Unsolved Ethical Issues in Paediatric Clinical Research
Helen Sammons, University of Nottingham, United Kingdom

Unsolved Ethical Issues in Geriatric Clinical Research
Jean-Pierre Baeyens, European Union Geriatric Medicine Society (EUGMS), Belgium

19:15 Dinner

Wednesday, 28 April 2010

8:00 Welcome Coffee

Plenary Session 1
Ethical Challenges in Paediatric Clinical Research

Chairpersons: Klaus Rose, Children’s Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany
Amparo Alemany Pozuelo, Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain

08:30 Impact of the Paediatric Regulation on the Clinical Trial Environment
Philippa Smit-Marshall, Paediatric Working Group, EUCROF & PharmaNet, The Netherlands

09:00 Ethical Aspects of the Paediatric Investigation Plans (PIPs)
Agnès Saint-Raymond, Human Medicines Special Areas, European Medicines Agency

09:30 Discussion

10:00 Coffee Break
Plenary Session 2
Ethical Challenges in Geriatric Clinical Research

Chairpersons: Florian von Raison, Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland
Anna Jurczynska, Paediatric Working Group, EUCROF & SERMES, Spain

10:30 Proposal for a Guideline on Performance of Clinical Trials in the Elderly Population
François Hirsch, INSERM, France

11:00 PREDICT: Increasing the PaRticipation of the ElDerl y In Clinical Trials
Peter Crome, PREDICT Project, University of Keele, United Kingdom

11:30 Discussion

12:00 Discussion: Complex Considerations for Ethics Committees on a Trial in a Vulnerable Population
Presenter of the “Difficult Case” and Facilitator: Michael Bone, Consultant Physician, EFGCP, United Kingdom

12:30 Lunch

Plenary Session 3
Lessons to be Learnt

Chairpersons: Soeren Rasmussen, Pfizer, USA (invited)
Frank Wells, Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom

13:30 Similarities and Differences of the Informed Consent Process in Children and Old People
Hugh Davies, National Research Ethics Service (NRES), United Kingdom

14:00 How Can Ethics Committees Ensure Adequate Expertise for the Review Paediatric and Geriatric Trials? – A Need for Training and Capacity Building
Petra Knupfer, Baden-Württemberg Ethics Committee, Germany

14:30 Discussion

15:00 Coffee Break

Chairpersons: Jean-Marc Husson, Geriatric Medicines Working Party, EFGCP & Eudipharm, France
Juergen Schaefer, Paediatric Working Group, EUCROF & Conreso, Germany

16:15 Closing Remarks
Martine Dehlinger-Kremer, Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
Ingrid Klingmann, Chairman of the Board, EFGCP & Pharmaplex, Belgium

16:20 End of the Workshop