

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

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Ethical Challenges in Clinical Research at both Ends of Life**  
Brussels, Belgium, 27 & 28 April 2010  
(Preliminary Programme, 10 February 2010 v)

## 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

<b>Amparo Alemany Pozuelo</b>	Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain
<b>Martine Dehlinger-Kremer</b>	Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
<b>Piergiorgio Galletti</b>	Paediatric Working Group, EUCROF & Hyperphar, Italy
<b>Jean-Marc Husson</b>	Geriatric Medicines Working Party, EFGCP & Eudipharm, France
<b>Ingrid Klingmann</b>	Chairman of the Board, EFGCP & Pharmaplex, Belgium
<b>Klaus Rose</b>	Children's Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany
<b>Florian von Raison</b>	Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland
<b>Frank Wells</b>	Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom

## Faculty

<b>Amparo Alemany Pozuelo</b>	Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain
<b>Jean-Pierre Baeyens</b>	European Union Geriatric Medicine Society (EUGMS), Belgium
<b>Michael Bone</b>	Consultant Physician, EFGCP, United Kingdom

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Peter Crome	PREDICT Project, University of Keele, United Kingdom
Hugh Davies	National Research Ethics Service (NRES), United Kingdom
Martine Dehlinger-Kremer	Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
Inés Galende	Investigation Research Area, Madrid Agency, Spain (invited)
François Hirsch	INSERM, France
Jean-Marc Husson	Geriatric Medicines Working Party, EFGCP & Eudipharm, France
Ingrid Klingmann	Chairman of the Board, EFGCP & Pharmaplex, Belgium
Anna Jurczynska	Paediatric Working Group, EUCROF & SERMES, Spain
Petra Knupfer	Baden-Württemberg Ethics Committee, Germany
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

## 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 **Ethics Committees' Experience with Deficiencies in Paediatric Study Protocols**  
*Hugh Davies, National Research Ethics Service (NRES), United Kingdom*
- 09:30 Discussion
- 10:00 Coffee Break

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**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 ELDerly 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:** *Inés Galende*, Investigation Research Area, Madrid Agency, Spain (invited)  
*Frank Wells*, Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom
- 13:30      **Ethical Aspects of the Paediatric Investigation Plans (PIPs)**  
*Agnès Saint-Raymond*, Human Medicines Special Areas, European Medicines Agency
- 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**
- 15:20      **Open Forum Discussion: What Can Be Learned from the Regulatory Approach to Paediatric Drug Development for the Encouragement for Drug Development for the Elderly**
- Chairpersons:** *Jean-Marc Husson*, Geriatric Medicines Working Party, EFGCP & Eudipharma, 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**