

EFGCP Annual Conference 2010  
*Aspects of Personalised Medicine for Society*  
*- A Challenge Yet to be Met*

Résidence Palace, Brussels, Belgium  
26 & 27 January 2010

*organised by the*

European Forum for Good Clinical Practice



*'where science & ethics meet'*

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## Conference Rationale

For the past 50 years the development of new medicines has been highly successful. As a result, many diseases have been well treated – sometimes cured or at least their symptoms relieved. Success could be measured by the number of patients thus treated. However, such success had to be leavened by the frequency of side effects and it had to be recognised that potential success for an individual patient could be nullified by the unacceptability of such side effects. So attempts were made both to increase the efficacy of new medicines and to improve their tolerability; and, in parallel, it was realised that efficacy and tolerability of any given medicine varied between individual patients. The traditional tools for finding the right dose for most patients were randomised controlled clinical trials and post-marketing surveillance studies; but, recently, the recognition that the individual genetic profiles of patients could be identified in terms of their susceptibility to treatment with medicines as well as their susceptibility to the side effects of such medicines has enabled a paradigm shift towards the success of a new medicine. Knowledge about the individual genome has clearly opened up huge scientific opportunities, but accompanied by a significant need to identify, discuss and attempt to solve aspects of personalised medicine related to society as a whole.

This conference will tackle the complex issues involved, including the ethics of providing confidential information arising from knowledge of the individual genome, associated economic factors, access to tailor-made treatment and how this should be prioritised. By means of a series of presentations by those experienced in handling these issues, and six interactive workshops, the EFGCP Annual Conference 2010 will aim to identify the challenges of personalised medicine in the context of society as a whole yet to be met. The various roles of all the stakeholders, from the bench-based scientist to the patient, will all be discussed in the interests of identifying the best possible treatments for the society of the future.

## Programme Committee

Frank O. Wells	Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Jean-Marc Husson	Eudiphar, EFGCP, France
Susan Trainor	Trainor and Partners, EFGCP, Belgium
Michael Bone	Consultant Physician, EFGCP, United Kingdom
Petra Knupfer	Baden-Württemberg Ethics Committee, Germany
Julie Kjelstrup	EuropaBio, Belgium
Richard Tiner	Faculty of Pharmaceutical Medicine, United Kingdom
Colin Wilsher	Pfizer, United Kingdom
Nicky Dodsworth	Premier Research Group, United Kingdom

## Faculty

Jean-Jacques Cassiman	University Hospital Leuven, Belgium
Elmar Doppelfeld	Permanent Working Party of the German Ethics Committees, Germany
David Gillen	Pfizer, United Kingdom
Jozef Glasa	Slovak Medical University in Bratislava; Member of the European Group on Ethics in Science and New Technologies, Slovakia

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**Aspects of Personalised Medicine for Society – a Challenge Yet to be Met**  
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(Preliminary Programme, 7 December 2009 v9)

Trish Groves	British Medical Journal, United Kingdom
David Haerry	European AIDS Treatment Group (EATG), Switzerland
JanHasker Jonkman	University of Groningen, EFGCP, The Netherlands
Alastair Kent	Genetic Interest Group (GIG), United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Olga Kubar	Pasteur Institute, EFGCP, Russia
Ludovic Lacaine	EuropaBio, Belgium
Malcolm Law	Queen Mary College University of London, United Kingdom
Gerd Mikus	University of Heidelberg, Germany
Detlef Niese	Novartis, Switzerland
Ysbrand Poortman	European Genetic Alliances' Network (EGAN), EFGCP, The Netherlands
Matthias Schwab	Margarete Fischer-Bosch Institute for Clinical Pharmacology, Germany
Cees Smit	Dutch Genetic Alliance (VSOP), the Netherlands
Erik Tambuyzer	Genzyme, Belgium
Jean-Pierre Tassignon	Crossover CRI, EFGCP, Switzerland
Henk ten Have	UNESCO, France
Arvo Tikk	Estonia
Richard Tiner	Independent Pharmaceutical Physician, United Kingdom
Susan Trainor	Trainor & Partners, EFGCP, Belgium
Joris Vermeesch	Catholic University of Leuven, Leuven, Belgium
Ronald Waife	Waife & Associates, Inc., USA
Markus Wartenberg	Das Lebenshaus e.V. - The Organisation for Patients with Rare Solid Tumours: GIST/Sarcomas/Kidney Cancer, Germany
Frank O. Wells	Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom

## Conference Language

The language of the Conference will be English.

## Social Event

On the evening of January 26<sup>th</sup>, all delegates are invited to take part in the Annual Conference social event. The 2010 edition will offer participants the chance to enjoy a privatised and guided visit of the Magritte Museum which opened its doors in 2009. The visit will be followed by the conference dinner.

# Agenda

Tuesday, 26 January 2010

- 08:00 Registration and Welcome Coffee
- 08:45 Welcome and Introduction to the Conference  
*Jean-Pierre Tassignon, Crossover CRI AG, EFGCP, Switzerland*
- 09:00 **Key Note Introduction** on: Current Status of Scientific Options to Personalise Treatment  
*Matthias Schwab, Dr. Margarete Fischer-Bosch Institute for Clinical Pharmacology, Germany*

## *Plenary Session 1*

### *What Do We Mean by "Personalised Medicine"?*

- Chairperson:** *Matthias Schwab, Dr. Margarete Fischer-Bosch Institute for Clinical Pharmacology, Germany*
- 09:35 "Personalised" Versus "Stratified" Medicines  
*Richard Tiner, Faculty of Pharmaceutical Medicine, United Kingdom*
- 10:05 Are there Communalities Between "Personalised Medicine" and "Orphan Treatment"?  
*Erik Tambuyzer, Genzyme, Belgium*
- 10:35 Coffee Break

## *Plenary Session 2*

### *The Societal Aspects of Genetic Testing*

- Chairperson:** *Detlef Niese, Novartis, Switzerland*
- 11:05 UNESCO's Recommendations for Personalized Medicine  
*Henk ten Have, UNESCO, France*
- 11:35 How Reliable is Today's Sequencing Technology Concerning Prediction of Potential Future Diseases and Should the Information be Commercially Available?  
*Speaker (invited)*
- 12:05 How Far Developed is Proactive Personalised Medicine (e.g. Based on Family History) and How Best to Inform Patients about Their Risk of Disease?  
*Speaker (invited)*
- 12:35 Panel and Open Forum Discussion:  
'Genetic Testing – How far can and should we go?'  
Chair: *Elmar Doppelfeld, Permanent Working Party of the German Ethics Committees, Germany*  
Panellists: *Session Chairs and Speakers from Sessions 1 and 2*

13:15 Lunch

### Workshops

14:15 **Workshop 1:** The Informed Consent Process in Clinical Trials Involving Genetic Testing  
Chair: *Gerd Mikus, University of Heidelberg, Germany*  
Rapporteur: *David Haerry, EATG, Switzerland*

**Workshop 2:** The Informed Consent Process on Future Research on Patient Tissues  
Chair: *Cees Smit, Dutch Genetic Alliance (VSOP), The Netherlands*  
Rapporteur: *Frank Wells, Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom*

**Workshop 3:** The Informed Consent Process in a Gene Therapy Trial  
Chair: *(invited)*  
Rapporteur: *(invited)*

15:30 Coffee Break

16:00 **Panel and Open Forum Discussion:**  
**Societal Consequences of Moving from Races to Genetic Categories**  
Chair: *Ronald Waife, Waife & Associates, Inc., USA*  
Panellists: *Markus Wartenberg, Das Lebenshaus e.V. - The Organisation for Patients with Rare Solid Tumours: GIST/Sarcomas/Kidney Cancer, Germany*

### Plenary Session 3

#### *The Joseph Hoet Lecture on Ethics in Clinical Research*

**Chairperson:** *Frank Wells, Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom*

16:45 Patients' Need for Better Treatment and Impact of Personalised Medicine on Society  
*Jean-Jacques Cassiman, Catholic University of Leuven, Leuven, Belgium*

17:30 EFGCP Annual General Meeting

18:30 EFGCP Annual Conference Social Event

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## Wednesday, 27 January 2010

08:00 Welcome Coffee

### Plenary Session 4

#### *The Societal Aspects of Access and Affordability of Personalised Treatment*

Chairperson: *Ludovic Lacaine, EuropaBio, Belgium*

08:30 Can the Development of Personalised Treatment be a Financially Viable Business Model?  
*Speaker (invited)*

09:00 Can Governments Afford to Refund Personalised Medicines?  
*Speaker (invited)*

09:30 Is a "Polypill" the Better Alternative?  
*Malcolm Law, Queen Mary College University of London, United Kingdom*

10:00 Coffee Break

### Workshops

10:30 **Workshop 4:** Criteria to Decide on Need and Affordability for Genetic Testing As a Basis For Treatment

Chair: *David Gillen, Pfizer, United Kingdom*

Rapporteur: *JanHasker Jonkman, University of Groningen, EFGCP, The Netherlands*

**Workshop 5:** Tracking and Storage of Personal Data in Registries and Biobanks – How to Handle the Conflict Between Researchers' Need for Information and the Patients' Needs for Data Protection??

Chair: *Olga Kubar, Pasteur Institute, EFGCP, Russia*

Rapporteur: *Arvo Tikk, Estonia*

**Workshop 6:** Pre-natal screening and Consequences of Knowing about Potential Future Diseases?

Chair: *Joris Vermeesch, Catholic University of Leuven, Leuven, Belgium*

Rapporteur: *Susan Trainor, Trainor & Partners, EFGCP, Belgium*

12:00 Lunch

### Plenary Session 5

#### *Reports from the Workshops*

Chairperson: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*

13:00 Rapporteur Workshop 1: *David Haerry, EATG, Switzerland*

Rapporteur Workshop 2: *Frank Wells, Cambridgeshire 4 Research Ethics Committee, EFGCP, United Kingdom*

Rapporteur Workshop 3: *(invited)*

Rapporteur Workshop 4: *JanHasker Jonkman, University of Groningen, EFGCP, The Netherlands*

Rapporteur Workshop 5: *Arvo Tikk, Estonia*

Rapporteur Workshop 6: *Susan Trainor, Trainor & Partners, EFGCP, Belgium*

14:30 Coffee Break

### *Plenary Session 6*

#### *The Need for Proper Education of the Public on Options and Limits of Gene Therapy and Diagnostics*

**Chairperson:** *Ysbrand Poortman, European Genetic Alliances Network, EFGCP, The Netherlands*

15:00 The Technological Options and Ethical Challenges of Nanotechnology in Medicine  
*Jozef Glasa, Slovak Medical University in Bratislava; Member of the European Group on Ethics in Science and New Technologies, Slovakia*

15:30 Patients with a Genetic Disease – When, How, by Whom Would They Want to be Informed About New Diagnostic and Treatment Options?  
*Alastair Kent, Genetic Interest Group (GIG), United Kingdom*

16:00 The Responsibility of the Journalist for Selection and Adaptation of News on Gene Therapy to the Reader (e.g. "Cigarette smoking reduces the chance to develop Parkinson Disease")  
*Trish Groves, British Medical Journal, United Kingdom*

16:30 Open Forum Discussion

**Chairperson:** *Alastair Kent, Genetic Interest Group (GIG), United Kingdom*

17:00 Closing Remarks  
*Jean-Pierre Tassignon, Crossover CRI AG, EFGCP, Switzerland*

End of the Conference