The EFGCP Annual Conference 2007

Ethics Committees in Europe - How to Work with Diversity?

Résidence Palace, Brussels, Belgium

30 January – 31 January 2007

organised by the

European Forum for Good Clinical Practice

'where science & ethics meet'

In Partnership with

European Medical Association (EMA)

World Medical Association (WMA)

Verband Forschender Arzneimittelhersteller (VFA)

European Clinical Research Infrastructures Network (ECRIN)

Programme Co-ordinators

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Frank O. Wells, Consultant, EFGCP, United Kingdom

Faculty

Kamran Abbasi	Journal of the Royal Society of Medicine, United Kindom
Jane Barrett	Barrett Consultancy, United Kingdom
Marc Bogaert	Belgian Advisory Committee on Bioethics, University of Gent, Belgium
Michael Bone	Association of Research Ethics Committees, United Kingdom
Xavier Carné	Hospital Clinic Barcelona, Spain
Sir Iain Chalmers	The James Lind Library, United Kingdom
Vincenzo Costigliola	European Medical Association, Belgium
Marek Czarkowski	Bioethics Committee of the Regional Chamber of Physicians and Dentists Warsaw, Poland
Hugh Davies	COREC, United Kingdom
Geneviève Decoster	IT & GCP Consulting, Belgium
Jacques Demotes	INSERM/ECRIN, EFGCP, France
Elmar Doppelfeld	Permanent Working Party of German Research Ethics Committees, Germany
Christiane Druml	Ethics Committee, University of Vienna, Austria
Alex Felice	University of Malta, Malta
Davina Ghersi	WHO Trial Register Platform, Switzerland
Jozef Glasa	University of Bratislava, EFGCP, Slovakia
David Haerry	EATG, Switzerland
Sylvie Hansel	Comité Consultatif de Protection, France
Charlotte Haug	Journal of the Norwegian Medical Association, Norway
Anne Kehely	Eli Lilly, United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Petra Knupfer	Baden-Württemberg Ethics Committee, Germany
Pierre Lafolie	Karolinska Institute, Sweden
Fabienne Lambert	EORTC, Belgium
Marianne Maman	Novartis Pharma, Switzerland
Mary O'Flaherty	Biogen, Ireland
Tamas Paál	National Institute of Pharmacy, Hungary
Monika Pietrek	PRA, Germany
Bernhard Schwetz	OHRP, United States of America
Ernst Singer	Ethics Committee, University of Vienna, Austria

Jiri Simek	Forum of Ethics Committees, Institute for Medical Ethics and Nursing, Charles University of Prague, Czech Republic
Gregory Sivolapenko	University of Patras, Greece
Jean-Pierre Tassignon	PSI Pharma Support, EFGCP, Switzerland
Richard Tiner	ABPI, United Kingdom
Helena van den Dungen	IGZ - Inspectorate of Health Care, The Netherlands
Frank Wells	Consultant, EFGCP, United Kingdom
Colin Wilsher	Pfizer, United Kingdom

Conference Rationale

During the past eighteen months, a group derived by the EFGCP Ethics Working Party has been collecting information from throughout Europe on the structure and functions of the ethics committees that were required to be established in accordance with the European Commission Directive on Clinical Trials (2001/20/EC). Whereas every Member State has indeed now adopted this directive, the exercise conducted by the EFGCP group has revealed that the manner in which the Directive has been implemented Member State by Member State has varied widely. This phenomenon of widely but nevertheless legitimate variation in the interpretation of an EC Directive is not uncommon, but, so long as these various interpretations are respected and well documented, it is quite acceptable. However, this exercise has revealed that in many parts of Europe there is very limited activity in important areas such as the training of research ethics committee members and quality assurance of ethics committees themselves.

The conference will address every one of the topics that have been covered by the report on this project and it is timed to coincide with the major launch of that report. The plenary sessions will be given by distinguished speakers from within and outside the European Union but can only cover a limited number of topics; the remaining topics will be the subject of interactive workshops from which reports will be received in the penultimate plenary session. During the conference a highly challenging lecture will be given by our Joseph Hoet Memorial Lecturer, Sir Iain Chalmers, formerly associated with the Cochrane Collaboration, but now Director of the James Lind Library.

Conference Language

The language of the Conference will be English.

Conference Dinner

On the evening of January 30th, all delegates are invited to take part to the conference social event.

Agenda

Tuesday, 30 January 2007

08:00 Registration and Welcome Coffee

09:00 Welcome and Introduction to the Conference
Jean-Pierre Tassignon, PSI Pharma Support, EFGCP, Switzerland

Plenary Session 1

Quality Assurance of Ethical Review

Chairpersons: *Pierre Lafolie, Karolinska Institute, Sweden*
Chair invited

09:05 How to ensure quality of Ethics Committees: How to apply Quality Assurance Audits to ECs?
Colin Wilsher, Worldwide Development Quality Assurance, Pfizer, United Kingdom

09:35 An Inspector's experiences in ethics committees inspections
Helena van den Dungen, IGZ - Inspectorate of Health Care, The Netherlands

10:05 An Ethics Committee's experience with an inspection
Ernst Singer, Ethics Committee, University of Vienna, Austria

10:35 Coffee Break

Plenary Session 2

Use of Safety Information

Chairperson: *Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom*

11:05 Importance of safety information
Anne Kehely, Eli Lilly, United Kingdom

11:35 Report from the European Union Network of Research Ethics Committees (EUREC) on the use of safety information in ECs
Michael Bone, Association of Research Ethics Committees (AREC), United Kingdom

12:05 The US approach to safety information handling by IRBs
Bernhard Schwetz, Office for Human Research Protections (OHRP), United States of America

12:35 **Panel and Open Forum Discussion:** "How to ensure optimal quality of ethical review in all EU countries?"

Panellists: *Speakers for this Session,*
plus *Jiri Simek, Forum of Ethics Committees, Institute for Medical Ethics and Nursing, Charles University of Prague, Czech Republic*
Vincenzo Costigliola, European Medical Association, Belgium

13:00 Lunch

Workshops

14.00 **Workshop 1:**
"Optimal composition of ethics committees"
Chair: *Marc Bogaert, Belgian Advisory Committee on Bioethics, University of Gent, Belgium*
Rapporteur: *Gregory Sivolapenko, University of Patras, Greece*

Workshop 2:
"Ethics committees and their money matters"
Chair: *Tamas Paál, National Institute of Pharmacy, Hungary*
Rapporteur*: Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom*

Workshop 3:
"Ethics Committees' review of indemnity conditions"
Chair: *Geneviève Decoster, IT & GCP Consulting, Belgium*
Rapporteur: *Marek Czarkowski, Bioethics Committee of the Regional Chamber of Physicians and Dentists Warsaw, Poland*

15:30 Coffee Break

16:00 **Panel and Open Forum Discussion:** "Training needs of ethics committees"

Chairperson: *Christiane Druml, Ethics Committee, University of Vienna, Austria*
Panellists: *Hugh Davies, Central Office for Research Ethics Committees (COREC), United Kingdom*
Sylvie Hansel, Comité Consultatif de Protection, France
Jacques Demotes, Institut National de la Santé et de la Recherche Médicale (INSERM), European Clinical Research Infrastructures Network (ECRIN), EFGCP, France

Plenary Session 3

The Joseph Hoet Lecture on Ethics in Clinical Research

Chairperson: *Frank Wells, Consultant, EFGCP, United Kingdom*

17:00 Is bioethics doing more harm than good to my interests as a patient?
Sir Iain Chalmers, the James Lind Library, United Kingdom

17:45 EFGCP Annual General Meeting

19:00 EFGCP Annual Conference Cultural Visit (departure from the Residence Palace)

20:30 EFGCP Annual Conference Cocktail and Dinner

Wednesday 31 January 2007

08:00 Welcome Coffee

Plenary Session 4

Ethics Approval Submission Strategies in Multinational Studies

Chairpersons: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*
Xavier Carné, Hospital Clinic Barcelona, Spain

08:30 Handling of EC applications in multinational clinical trials
Fabienne Lambert, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

09:00 How to handle patient information and informed consent preparation in multinational clinical trials
Monika Pietrek, PRA, Germany

09:30 Differences of opinion between ethics committees in different countries and health authorities on approvability of clinical trials
Speaker invited

10:00 Coffee break

Workshops

10:30 **Workshop 4:**
"Assessment of investigator suitability"
Chair: *Petra Knupfer, Baden-Württemberg Ethics Committee, Germany*
Rapporteur: *Alex Felice, Dept of Medical Genetics, University of Malta*

Workshop 5:
"Patient information and informed consent in the unconscious patients"
Chair: *Marianne Maman, Clinical Development & Medical Affairs, Ext. Relations, Novartis Pharma, Switzerland*
Rapporteur: *Mary O'Flaherty, Biogen, Ireland*

Workshop 6:
"Patient information and informed consent in under-privileged patients"
Chair: *Jane Barrett, The Barrett Consultancy, United Kingdom*
Rapporteur: *David Haerry, European AIDS Treatment Group, Switzerland*

12:00 Lunch

Plenary Session 5

Reports from the Workshops

Chairpersons: *Ingrid Klingmann, Pharmaplex, EFGCP, Belgium*
Frank Wells, Consultant, EFGCP, United Kingdom

13.00 Rapporteur Workshop 1: *Gregory Sivolapenko, University of Patras, Greece*

Rapporteur Workshop 2: *Richard Tiner, ABPI, United Kingdom*

Rapporteur Workshop 3: *Marek Czarkowski, Bioethics Committee of the Regional Chamber of Physicians and Dentists Warsaw, Poland*

Rapporteur Workshop 4: *Alex Felice, Dept of Medical Genetics, University of Malta*

Rapporteur Workshop 5: *Mary O'Flaherty, Biogen, Ireland*

Rapporteur Workshop 6: *David Haerry, European AIDS Treatment Group (EATG)*

14:30 Coffee break

Plenary Session 6

Conflicts of interest in clinical research

15.00 **Forum Discussion**:
Chairpersons: *Jean-Pierre Tassignon, PSI Pharma Support, EFGCP, Switzerland*
Jozef Glasa, University of Bratislava, EFGCP, Slovakia

Introduction:
Ethical responsibilities to publish?
Kamran Abbasi, Journal of the Royal Society of Medicine, United Kingdom

Panelists: *Charlotte Haug, Editor, Journal of the Norwegian Medical Association & COPE, Norway*
Davina Ghersi, Coordinator, WHO Trial Register Platform, Switzerland
Elmar Doppelfeld, Chairman, Permanent Working Party of German Research Ethics Committees, Germany
John Saunders, Royal College of Physicians, United Kingdom

16.45 Closing remarks

17:00 End of the Conference