

The EFGCP Annual Conference 2009

Research Integrity: a European Perspective

Diplomat Hotel, Prague, Czech Republic

27 - 28 January 2009

organised by the

European Forum for Good Clinical Practice



'where science & ethics meet'

In Partnership with

Czech Science Foundation (CSF)
Czech Ministry of Health (Department of Education and Science)
1st School of Medicine, Charles University, Prague
European Science Foundation (ESF)
Association of the British Pharmaceutical Industry (ABPI)
Association of Clinical Research Professionals (ACRP)
Institute of Clinical Research (ICR)

Programme Committee

Frank Wells	Retired Pharmaceutical Physician, EFGCP, United Kingdom
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Jean-Marc Husson	Eudipharm, EFGCP, France
Marianne Maman	Novartis, Switzerland
Jiri Simek	Forum of Ethics Committees, Charles University of Prague, Czech Republic
Paul Strickland	Amgen, EFGCP, United Kingdom
Jozef Syka	Czech Science Foundation, Czech Republic
Susan Trainor	Trainor and Partners, EFGCP, Belgium

Faculty

Jane Barrett	The Barrett Consultancy, United Kingdom
Pierre-Henri Bertoye	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France
Jean-Pierre Boissel	University Claude Bernard of Lyon, France
Michael Bone	Association of Research Ethics Committees (AREC), United Kingdom
Marc Buyse	International Drug Development Institute (IDDI), Belgium
Jacques Demotes	INSERM, European Clinical Research Infrastructures Network (ECRIN), France
Nicky Dodsworth	Premier Research Group, United Kingdom
Michael Farthing	University of Sussex, United Kingdom
Erick Gaussens	ProductLife, France
Jozef Glasa	Institute of Medical Ethics and Bioethics, Postgraduate School of Medicine, Bratislava, EFGCP, Slovakia
Jean-Marc Husson	EudiPharm, EFGCP, France
Helena Illnerova	Committee for Scientific Integrity, Czech Academy of Sciences, Czech Republic
Peter Jay	MedicoLegal Investigations, United Kingdom
JanHasker G. Jonkman	University of Groningen, The Netherlands
Marcel Kenter	Central Committee on Research inv. Human Subjects (CCMO), The Netherlands
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Petra Knupfer	Baden-Württemberg Ethics Committee, Germany
Olga Kubar	Pasteur Institute, EFGCP, Russia
Josef Kuře	Bioethics Committee, Czech Governmental Research and Development Council, Czech Republic

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(*Preliminary Programme, 12 January 2009 v15*)

Pierre Lafolie	Stockholm Regional Ethical Review Board, Sweden
Marianne Maman	Novartis, Switzerland
Ana Marusic	Croatian Medical Journal & Council of Science Editors, Croatia
Nicholas Moore	University of Bordeaux, France
Tamas Paál	National Institute of Pharmacy, Hungary
Yannick Plétan	Pfizer, France
Melvyn Rapprecht	F. Hoffmann-La Roche, Switzerland
Drummond Rennie	University of California San Francisco, USA
Povl Riis	Emeritus Professor of Medicine, Copenhagen, Denmark
Jiri Simek	Forum of Ethics Committees, Charles University of Prague, Czech Republic
Nicholas Steneck	University of Michigan and Office for Research Integrity (ORI), USA
Paul Strickland	Amgen, EFGCP, United Kingdom
Fergus Sweeney	European Medicines Agency (EMA)
Matthew Sydes	Medical Research Council (MRC), United Kingdom
Jozef Syka	Czech Science Foundation, Czech Republic
Jean-Pierre Tassignon	Crossover CRI AG, EFGCP, Switzerland
Richard Tiner	Association of the British Pharmaceutical Industry (ABPI), United Kingdom
Susan Trainor	Trainor and Partners, EFGCP, Belgium
Kristel Van de Voorde	Bristol-Myers Squibb, Belgium
Frank Wells	EFGCP, United Kingdom
Colin Wilsher	Pfizer, United Kingdom

Conference Rationale

The First World Conference on Research Integrity, held in Lisbon in September 2007, yielded many aspects of fraud and misconduct in scientific research that justify the development of better techniques for the prevention, detection, investigation and prosecution of such misconduct, throughout the world. Europe has a variable track record in tackling this problem, but many bodies, as well as individuals, have had some success in this objective. By means of a series of presentations from those experienced in handling this problem, on a world-wide basis, and of workshops, this conference will present an opportunity to explore in depth how individuals and institutions in Europe can demonstrate a commitment to research integrity, specifically in the field of biomedical research.

Conference Language

The language of the Conference will be English.

Conference Dinner

On the evening of January 27th, all delegates are invited to take part in the conference social event.

Agenda

Tuesday, 27 January 2009

- 08:00 Registration and Welcome Coffee
- 08:45 Welcome and Introduction to the Conference
Jean-Pierre Tassignon, President, Crossover CRI AG, Chairman of the Board, EFGCP, Switzerland
Minister of Health, Czech Republic (invited)
Joseph Syka, Immediate Past-President, Czech Science Foundation, Czech Republic

Plenary Session 1

The Responsible Performance of Clinical Trials

- Chairpersons: *Jean-Marc Husson*, EudiPharm, EFGCP, France
Jozef Glasa, Institute of Medical Ethics and Bioethics, Postgraduate School of Medicine, Bratislava, EFGCP, Slovakia
- 09:05 The Ethical Conduct of Clinical Research
Pierre Lafolie, Stockholm Regional Ethical Review Board, Sweden
- 09:35 Ethical Issues in the Publication Process
Ana Marusic, Croatian Medical Journal & Council of Science Editors, Croatia
- 10:05 The Role of Research Ethics Committees in Maintaining Integrity
Marcel Kenter, Central Committee on Research inv. Human Subjects (CCMO), The Netherlands
- 10:35 Coffee Break

Plenary Session 2

The Historical Aspects of Research Misconduct

- Chairpersons: *Michael Farthing*, University of Sussex, United Kingdom
Jacques Demotes, INSERM, European Clinical Research Infrastructures Network (ECRIN), France
- 11:05 North America
Nicholas Steneck, University of Michigan and Office for Research Integrity (ORI), USA
- 11:35 Europe
Frank Wells, EFGCP, United Kingdom
- 12:05 Identifying potential problems in a timely fashion
Melvyn Rapprecht, Clinical Quality Assurance, F. Hoffmann-La Roche, Switzerland

12:35 Panel and Open Forum Discussion:
'Integrity in Biomedical Clinical Research: Does it Matter?'
Chair: *Povl Riis, Denmark*
Panellists: *Session Chairs and Speakers*

13:00 Lunch

Workshops

14:00 Workshop 1: The role of monitoring in the detection of misconduct
Chair: *Yannick Pletan, Pfizer, France*
Rapporteur: *Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom*

Workshop 2: The role of audit in the detection of fraud
Chair: *Paul Strickland, Amgen, EFGCP, United Kingdom*
Rapporteur: *Kristel Van de Voorde, Bristol-Myers Squibb, Belgium*

Workshop 3: The role of research ethics committees in preventing misconduct
Chair: *Petra Knupfer, Baden-Württemberg Ethics Committee, Germany*
Rapporteur: *Michael Bone, Association of Research Ethics Committees (AREC), United Kingdom*

15:30 Coffee Break

16:00 Panel and Open Forum Discussion:
'What is Misconduct and What is Fraud?'
Chair: *Helena Illnerova, Committee for Scientific Integrity, Czech Academy of Sciences, Czech Republic*
Panellists: *Jacques Demotes, INSERM, European Clinical Research Infrastructures Network (ECRIN), France*
Yannick Plétan, Pfizer, France
Fergus Sweeney, European Medicines Agency (EMA)
Josef Kuře, Bioethics Committee, Czech Governmental Research and Development Council, Czech Republic

Plenary Session 3

The Joseph J. Hoet Lecture on Ethics in Clinical Research

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

17:00 "No Truth: No Consequences."
Why Regulations Must be Universal, Enforced and Immediate.
Drummond Rennie, University of California San Francisco, USA

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17:45 EFGCP Annual General Meeting
18:45 EFGCP Annual Conference Social Event

Wednesday, 28 January 2009

08:00 Welcome Coffee

Plenary Session 4

Whistleblowing

Chairpersons: *Marianne Maman*, Novartis, Switzerland
Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom

08:30 The role of the whistleblower
Nicholas Moore, University of Bordeaux, France

09:00 How to handle the whistleblower
Jane Barrett, The Barrett Consultancy, United Kingdom

09:30 The role of the whistleblower in a post-communist country
Jiri Simek, Forum of Ethics Committees, Charles University of Prague, Czech Republic

10:00 Coffee Break

Workshops

10:30 Workshop 4: Can statistical analysis reveal research misconduct?
Chair: *Matthew Sydes*, Clinical Trials Unit, Medical Research Council (MRC), United Kingdom
Rapporteur: *Marc Buyse*, International Drug Development Institute (IDDI), Belgium

Workshop 5: Conduct of an enquiry into alleged misconduct
Chair: *Peter Jay*, MedicoLegal Investigations, United Kingdom
Rapporteur: *Olga Kubar*, Pasteur Institute, EFGCP, Russia

Workshop 6: The role of national competent authorities
Chair: *Tamas Paál*, National Institute of Pharmacy, Hungary
Rapporteur: *JanHasker G. Jonkman*, University of Groningen, The Netherlands

12:00 Lunch

Plenary Session 5

Reports from the Workshops

- Chairpersons: *Jiri Simek, Forum of Ethics Committees, Charles University of Prague, Czech Republic*
Frank Wells, Consultant, EFGCP, United Kingdom
- 13:00 Rapporteur Workshop 1: *Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom*
 Rapporteur Workshop 2: *Kristel Vandervoerde, Bristol-Myers Squibb, Belgium (invited)*
 Rapporteur Workshop 3: *Michael Bone, Association of Research Ethics Committees (AREC), United Kingdom*
 Rapporteur Workshop 4: *Marc Buyse, International Institute for Drug Development, France*
 Rapporteur Workshop 5: *Olga Kubar, Pasteur Institute, EFGCP, Russia*
 Rapporteur Workshop 6: *JanHasker Jonkman, University of Groningen, The Netherlands*
- 14:30 Coffee Break

Plenary Session 6

Factors Affecting Research Behaviour and Integrity

- Chairpersons: *Colin Wilsher, Pfizer, United Kingdom*
Susan Trainor, Trainor & Partners, EFGCP, Belgium
- 15:00 The role of education of investigators in research integrity
Jean-Pierre Boissel, University Claude Bernard of Lyon, France
- 15:30 The role of routine enhanced audit
Nicky Dodsworth, Premier Research Group, United Kingdom
- 16:00 The future role of electronic tracking in monitoring data outputs
Erick Gaussens, ProductLife, France
- 16.25 Feedback on French and European inspection experience : programmes and findings
Pierre-Henri Bertoye, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France
- 16:50 Closing Remarks
Jean-Pierre Tassignon, President, Crossover CRI AG, Chairman of the Board, EFGCP, Switzerland
Joseph Syka, Immediate Past-President, Czech Science Foundation, Czech Republic
- 17.00 End of the Conference