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

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)
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 worldwide 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.

Programme Committee

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<th>Name</th>
<th>Institution/Position</th>
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Faculty

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<td>Yannick Plétan</td>
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<td>Colin Wilsher</td>
<td>Pfizer, United Kingdom</td>
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Conference Language

The language of the Conference was English.

Conference Social Event

On the evening of January 27th, all delegates were invited to take part in the conference social event. The participants had the privilege to sit in the Aula Magna of Charles University and listen to a concert of the Mixed choir Gaudium Pragense before enjoying a friendly buffet dinner full of Czech specialties.

About Karolinum (Charles University) & the Aula Magna:

When Charles IV founded Charles University in 1348 he stressed out that it was the first university in the central Europe. There were four faculties at that time: faculty of art, medical faculty, faculty of law and theological faculty. The lectures were given first in churches, monasteries or private flats. Charles College was founded in 1366, seated in the Jewish quarter. The teachers and students realised more and more that they needed a building that would represent the university. That's why the son of Charles IV, Wenceslas IV., bought for the university an imposing Gothic house of Jan Rotlev and added two other houses. These buildings were reconstructed for the university purposes and Charles College moved into the new complex – Karolinum (Karolinum).

The buildings were extended – a new university chapel and a big hall for ceremonial assemblies – aula magna – were built. The university had lecture-rooms, assembly halls, flats for lecturers, a spa and even a prison. The university building experienced a lot of events important in the Czech history. Professor and rector John Huss used to give lectures here. After 1620 the university was taken over by the Jesuits. They connected Karolinum with their college in Clementinum.

Carolinum’s pride is the big aula which is used for university celebrations and graduation ceremonies. The main wall is decorated by a tapestry with the motive of Charles IV kneeling in front of St. Wenceslas. In front the tapestry there is a bronze statue of Charles IV.

The chapel, arcade and walls of Karolinum still survive. Notice especially a fine Gothic oriel window from 1370. When walking in the centre of Prague, don’t miss Karolinum where the important history has been written. Karolinum is open during ceremonies, special events or open-door days.

(source: http://www.prague.net/carolinum)

About the Gaudium Pragense Choir:

The mixed choir Gaudium Pragense was formed in 1989. It consists of around 45 persons, who have decided to devote their free time to chamber choral music. For the first decade of its existence the choir was under the artistic direction of Prof. J. Smutný. The present music director and conductor is Lukáš Hurník. More than 10 years the choir is accompanied by Jana Hurníková on the organ, during rehearsals and concerts. She graduated in the 1962 from the Music Faculty of Academy of Performing Arts in Prague, under supervision of Ilona Štěpánová-Kurzová.

The choir performs a varied repertoire ranging from renaissance music to 20th century works. A significant part of its repertoire is made up of baroque and classical compositions by Czech composers.

The choir gives a’capella concerts as well as joining forces with organ accompaniment and other instruments. It also establishes relations with choirs from other countries in order to contribute to the advancement of piece and friendship in the world on the basis of a common culture.

(source: http://www.gaudiumpragense.cz)
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
Josef Syka, Immediate Past-President, Czech Science Foundation, Institute of Experimental Medicine, Academy of Sciences, Czech Republic

Plenary Session 1

The Responsible Performance of Clinical Trials

Chairpersons: Jean-Marc Husson, European Diploma in Pharmaceutical Medicine (Eudipharma), 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, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, 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 Rapprech, 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, Emeritus Professor of Medicine, Age Forum (State Council on Age Politics and Research), 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 Plétan, 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 & Medical Association Landesärztekammer, 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, Academy of Sciences of the Czech Republic
Panellists: Jacques Demotes, European Clinical Research Infrastructures Network (ECRIN), INSERM, EFGCP, France
Yannick Plétan, Pfizer, France
Fergus Sweeney, European Medicines Agency (EMEA)
Josef Kuří, 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

17:45  EFGCP Annual General Assembly Meeting
18:45  EFGCP Annual Conference Social Event
Wednesday, 28 January 2009

Plenary Session 4

Whistleblowing

Chairpersons: Marianne Maman, Novartis Pharma, 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, Faculty of Health & Social Studies, University of South Bohemia in Ceske Budejovice, 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: Pierre Mallia, University of Malta, Malta

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, Faculty of Health & Social Studies, University of South Bohemia in Ceske Budejovice, Czech Republic
Frank Wells, EFGCP, United Kingdom

13:00 Rapporteur Workshop 1: Richard Tiner, Association of the British Pharmaceutical Industry (ABPI), United Kingdom
Rapporteur Workshop 2: Kristel Van de Voorde, Bristol-Myers Squibb, Belgium
Rapporteur Workshop 3: Michael Bone, Association of Research Ethics Committees (AREC), EFGCP, United Kingdom
Rapporteur Workshop 4: Marc Buyse, International Institute for Drug Development, France
Rapporteur Workshop 5: Frank Wells, Consultant, EFGCP, United Kingdom
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 International, 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
Jean-Marc Husson, European Diploma in Pharmaceutical Medicine (Eudipharm), EFGCP, 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
Josef Syka, Immediate Past-President, Czech Science Foundation, Institute of Experimental Medicine, Academy of Sciences, Czech Republic

17:00 End of the Conference