



'where science and ethics meet'

ANNUAL REPORT OF ACTIVITIES 2009

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STRUCTURE

General Assembly

As usual, EFGCP organised its Annual General Meeting during its Annual Conference, on 27 January 2009 in Prague, Czech Republic. The accounts and report of activities for 2008 were presented and the EFGCP Officers were relieved of their responsibility for the 2008 accounts.

Board

Six Board meetings were organised on a regular basis from January to December:

- 27 January 2009, Diplomat Hotel, Prague, Czech Republic
- 24 March 2009, EFGCP Office, Brussels, Belgium
- 18 May 2009, EFGCP Office, Brussels, Belgium
- 6 July 2009, EFGCP Office, Brussels, Belgium
- 15 September 2009, EFGCP Office, Brussels, Belgium
- 7 December 2009, EFGCP Office, Brussels, Belgium

The EFGCP Board of Directors in 2009 was composed of the following members and officers:

Dr. Jean-Pierre Tassignon	Chairman
Prof. Jacques Demotes-Mainard	Vice-Chairman
Dr. Yves Geysels	Treasurer & Membership Officer
Dr. Michael Bone	Secretary
Dr. Ingrid Klingmann	Conference Officer, Co-Chairperson, Ethics Working Party & Patients' Roadmap to Treatment Working Party (in collaboration with EGAN)
Mrs. Susan Trainor	Organisation Development & Publications Officer
Dr. Frank Wells	Ethics Officer, Co-Chairman, Ethics Working Party
Prof. Olga Kubar	Education Officer
Prof. Jean-Marc Husson	Co-Chairman, Geriatric Medicines Working Party
Mrs. Vesna Vujaklija	Chairperson, Education Working Party
Mr. Paul Strickland	Chairman, Audit Working Party
Dr. Klaus Rose	Chairman, Children's Medicines Working Party
Mr. Ysbrand Poortman	Co-Chairperson, Patients' Roadmap to Treatment Working Party (in collaboration with EGAN)
Dr. Florian von Raison	Co-Chairman, Geriatric Medicines Working Party
Prof.Dr. JanHasker G. Jonkman	Board Member

Dr. Jean-Pierre Girre	Board Member
Prof.Dr. Jozef Glasa	Board Member
Mr. Gerard J Marsat	Board Member

Bureau

The EFGCP Bureau is the organisational arm of the EFGCP responsible for all the operational aspects of the association and its activities including membership services. All the EFGCP events continued to be managed internally in 2009 with the additional help of a trainee or an interim employee supported by the 'Maribel grant', a public fund open to associations to which EFGCP submits its candidacy whenever the call is relevant.

The EFGCP team is composed of 3 members:

Fanny Senez, Chief Operating Officer

Pauline Havelange, Admin. & Finances Coordinator

Corinne Gaillard, Projects Coordinator

The EFGCP office located in the European district of Brussels also welcomes the European Platform for Patients' Organisations, Science & Industry (EPPOSI) within a sub-lease agreement.

MEMBERSHIP IN 2009

Membership in the EFGCP is open to professionals and individuals, representing patient groups, ethics committees, academic & industry research enterprises, regulatory officials, and those concerned to develop Good Clinical Practice in Europe.

Individual Membership

In 2009, 197 members have joined EFGCP or renewed their membership, which represents an increase of 10 members compared to 2008. In 5 years, the EFGCP membership more than doubled (2004: 95 members)

Overview by category (

Profiles	2005	2006	2007	2008	2009
Academia & Ethics Committee	38	45	44	46	54
Biotech Industry	9	8	4	4	5
CRO	14	18	11	16	25
Government/Regulatory	8	14	10	15	13
NGO	6	8	8	18	10
Patient Organisation	ND	1	4	5	5
Pharma Industry	50	50	47	66	65
Students & Retired Members	ND	1	2	4	9
Other (Consultant, Editor, ...)	9	12	17	13	11
TOTAL	134	157	147	187	197

ND = Not Defined

Overview by Country

Country TOTAL	Country count TOTAL
Australia	1
Austria	2
Belgium	34
Bosnia and Herzegovina	2
Croatia	2
Cyprus*	1
Czech Republic	2
Denmark	7
Finland*	4
France	14
Georgia	1
Germany	17
Greece	2
Hungary	3
India*	1
Ireland	3
Italy	6
Japan	1
Kazakhstan*	1

Luxemburg	2
Norway	1
Poland	1
Republic of Macedonia*	1
Romania	1
Russia	3
Saudi Arabia	1
Serbia	1
Slovak Republic	1
Slovenia	1
South Africa*	1
Spain*	2
Sweden	4
Switzerland	16
The Netherlands	13
Ukraine	1
United Kingdom	33
United States of America	10
TOTAL	37 Countries
	197 members

* new countries, compared with 2008

Corporate Membership

The launch of this new initiative in 2008 is testimony to EFGCP's commitment to build long term relationships with companies in the field of biomedical research. EFGCP is moving away from the previous model of offering ad-hoc sponsorship opportunities and is now in a position to offer companies solid and attractive benefits and create partnerships in order to work together for the worthy cause of promoting good clinical practice. Membership packages and fees were revised in 2009 to adapt to the economical conditions faced by all types and sizes of companies.

The EFGCP now counts 6 Corporate Members as follows:

Silver Members:



NOVARTIS

Bronze Members:



Institutional Membership

As announced in early 2009, EFGCP has launched the Institutional Membership in order to formalise and promote its existing partnerships with other not-for-profit organisations (patient organisations, associations...). A Memorandum of Understanding (MOU) was drafted to set out a framework of co-operation between EFGCP and the other institution to encourage:

- Communication and interaction between the two organisations;
- Exchange of newsletters;
- Exchange of ideas, information and data regarding conferences;
- Networking between other organisations with which EFGCP and Organisation X are regularly in contact.

The first invited and confirmed Institutional Members in 2009 were:



Institutional Membership is intended to be further stressed and promoted in 2010.

EVENTS 2009

EFGCP CONFERENCES

EFGCP Annual Conference 2009 on Research Integrity: a European Perspective

In partnership with the Association of the British Pharmaceutical Industry (ABPI), the Association of Clinical Research Professionals (ACRP), the Czech Science Foundation (CSF), the European Science Foundation, the First School of Medicine (Charles University, Prague), Novartis and the Regulatory Affairs Professionals Society (RAPS)

Diplomat Hotel, Prague, Czech Republic, 27-28 January 2009

Open meeting

Number of participants: 118

Report: available on the website & in the EFGCP News – Spring 09 Issue

EFGCP-AREC Workshop on Research Ethics Committee Complex Cases - The Older Participant

In partnership with the Association of Research Ethics Committees (AREC)

The Wildt'sches Haus, Basel, Switzerland, 15 January 2009

Open meeting

Number of participants: 21

PatientPartner Project Start-Up Central Workshop on Patients Partnering in Clinical Research

Organised by EFGCP on behalf of the PatientPartner project

Marivaux Hotel Congress & Seminar Centre, Brussels, Belgium, 11 June 2009

Open Meeting

Number of participants: 75

Report: available on the website & in the EFGCP News – Autumn 09 Issue

EFGCP Multidisciplinary Workshop on A Single CTA in Multinational Clinical Trials: Dream or Option?

Diamant Centre, Brussels, Belgium, 7 July 2009

Open meeting

Number of participants: 84

Report: available on the website & in the EFGCP News – Autumn 09 Issue

PatientPartner North-Western European Regional Workshop on Defining the needs and means for more Partnership between Patients, Patient Organisations and Other Stakeholders in Clinical Trials

Organised by EFGCP on behalf of the PatientPartner project

Central Hall Westminster, London, United Kingdom, 12 & 13 October 2009

Open Meeting

Number of participants: 81

Report: available after end March 2010 on the website

EFGCP Geriatric Medicines Working Party Workshop on The challenge of an ageing population for medical research: Is Europe ready to cope?

Résidence Palace, Brussels, Belgium, 19 & 20 November 2009

Open Meeting

Number of participants: 46

Report: available on the website & soon in the next issue of the EFGCP News

PatientPartner Central-Eastern European Regional Workshop on Defining the needs and means for more Partnership between Patients, Patient Organisations and Other Stakeholders in Clinical Trials

Organised by EFGCP on behalf of the PatientPartner project

Marriott Hotel, Budapest, Hungary, 30 November & 1 December 2009

Open Meeting

Number of participants: 43

Report: available after end March 2010 on the website

CONFERENCES IN PARTNERSHIP WITH EFGCP

Workshop on Clinical Trials - Shaping the Future of European Clinical Research Legislation

organised by EPPOSI; supported and co-chaired by EFGCP

Diamant Centre, Brussels, Belgium, 22 April 2009

Multidisciplinary Workshop on Innovative Approaches to Clinical Trials Co-Sponsorship in the EU

organised by the EBMT and CLINT Project as part of the new Road Map Initiative for Clinical Research in Europe

Hammersmith Hospital, London, United Kingdom, 21 September 2009

EFGCP Children's Medicines Working Party 5th Annual Conference on Integrating Paediatrics into Drug Development – From Concept to Reality

Joint with DIA 3rd Paediatric Forum

Hotel Radisson Edwardian New Providence Wharf, London, United Kingdom, 27-28 October 2009

Conference on Promoting children's participation in research: Children should be seen and heard

Joint NRES-EFGCP-INVOLVE-RCPCH

Hotel Russell, London, United Kingdom, 23 November 2009

WORKING PARTIES

The EFGCP Working Parties serve as the central reference point for EFGCP research and the development of European guidance, reports, and publications in the area of Good Clinical Practice. The Working Parties are open to all EFGCP members, with expertise and interest in contemporary areas such as the ethics, science, and regulation of clinical research in Europe and globally.

The active five Working Parties are the following:

AUDIT WORKING PARTY (AWP)

- **42 Members**
- **Chair:** Mr. Paul Strickland, Amgen Ltd., UK
- **Aim:** The Audit Working Party examines ethical, safety, and data oversight issues in clinical research. Its primary focus is on the work of the professional clinical trial auditor, with a view toward the regulatory and legal issues that distinguish this expertise. The Audit Working Party also looks at issues related to clinical trial monitoring and inspection. It is particularly concerned with the development of European standards for monitoring clinical trials, ethics committees, and sponsor-related responsibilities. It provides a framework for considering the impact and development of a European clinical trials inspection system within the context of sponsor, investigator, and ethics committee responsibilities.

- **Report of Activities 2009**

The EFGCP Audit Working Party continues to experience a healthy turn-over in its membership. New members have been joining through the year, largely by word of mouth. Some members sometimes find difficulties in attending meetings, and the WP will ask for replacements where this means major organisations are unrepresented.

As usual, three meetings have been held this year, in Prague, Paris and the UK.

Annual conference

Members of the AWP chaired and reported a session on the role of auditing in the handling of scientific misconduct and fraud.

Pharmacovigilance Master File

Members have actively lobbied regulators and Parliamentary members to oppose the introduction of mandatory disclosure of audit findings to regulatory inspectors. This initiative began in the AWP but has spread throughout the EFGCP. Our most recent move has been to contact the chairs of the committees who will deliberate this issue.

Role of QAU

AWP guidance on the role of a quality assurance unit in clinical trials was published in the International Journal of Pharmaceutical Medicine. This was very well received.

Contract QA

A sub-group of the AWP is currently producing a guideline on the many aspects and types of contract quality assurance.

Misconduct and Fraud

A subgroup of the AWP is participating in the EWP guide on misconduct, contributing a section on the role of audit in misconduct.

Speciality meeting

The UK meeting of the AWP included a speciality session on clinical trial insurance, assisted by presentations from members of Aon. This is a very contentious topic within clinical research, especially in the UK, and the meeting was very helpful in clarifying industry norms and what possible solutions exist.

Benchmarking

One of the strengths of the AWP is the opportunity for benchmarking across the members. Several surveys have been run and summarised including:

- Investigator training
- Criticality definitions
- Scope of the audit universe

- **Planned Meetings in 2010**

25 January, Residence Palace, Brussels, to coincide with the EFGCP annual conference;
15 June in Copenhagen as guests of Lundbeck;
19 October in the UK (Gerrards Cross - West of London) as guests of Daiichi Sankyo.

CHILDREN'S MEDICINES WORKING PARTY

- **55 Members**

- **Chair:** Dr. Klaus Rose, Granzer Regulatory Consulting & Services, CH

- **Aim:** The EFGCP Children's Medicines Working Party facilitates the discussion in Europe towards a broader public agreement on the needs for better medicines for children. It focuses on the development of an ethical and scientific framework for clinical research for children that is supported by the developing European regulatory framework in paediatric clinical trials. The EFGCP uses its traditional strength in consensus building in forming a coalition of core representatives from pediatricians & academia, regulatory authorities, patients' & parents' organisations, ethical committees and the research-friendly media on a European level.

- **Report of Activities 2009**

With the EU Pediatric Regulation now in force since 3 years, the EFGCP Children's Medicines Working Party is now in the process of re-assessing its role. The pediatric conference in 2008 had been successful with around 100 participants from regulatory authorities, academia, and pharmaceutical industry. In 2009 we decided to merge our conference with the DIA pediatric conference for the years 2009 and 2010. This on the background that pediatric drug development is reaching a more mature stage, where the need of general awareness making is much lower than it some years ago. For major companies the submission of pediatric investigation plans (PIPs) has reached a stage of preliminary routine, more and more medium and small size companies have first experiences with PIPs, and now the first PUMA (Pediatric Use Marketing Authorisation, for off-patent drugs) PIPs have been approved. On one side conference participants today ask more for practical advice how to prepare, negotiate and later execute PIPs, on the other side these conferences are a valuable key opportunity to have a direct dialogue with key decision makers in regulatory authorities, with key clinicians involved in pediatric clinical care and research, parents & patients, industry people, and other professionals involved in pediatric drug development. This dialogue is not limited to an exchange of practicalities, but is also essential to influence the decision makers how in the near and later future requests for pediatric development will be handled.

The October 2009 joint conference of the EFGCP Children's Medicines Working Party and the DIA pediatric SIAC (Special Interest Area Committee) was very successful, with a special focus on pediatric oncology and a lively update on the state of affairs of pediatric drug development in Europe.

- **Planned Activities in 2010**

The preparation of the 2010 joined EFGCP and DIA pediatric conference will begin in January 2010, it is preliminarily planned for October 2010. The positive experience of the London meeting, where many EMEA participants joined the conference on short notice, has lead us to the decision that the 2010 conference will again be in London.

If you have any questions, don't hesitate to contact Klaus Rose at rose@granzer.biz.

ETHICS WORKING PARTY (EWP)

- **47 Members**
- **Co-chair:** Dr. Ingrid Klingmann, Pharmaplex, BE
Co-chair: Dr. Frank Wells, EFGCP, UK
- **Aim:** The Ethics Working Party focuses on reflection and education regarding the ethics of biomedical research, particularly within the context of Good Clinical Practice. The focuses are primarily on the ethical review process, contemporary ethical issues in clinical research, and informed consent at the European and transnational levels within a global perspective. This is an international, multi-disciplinary, multi-sectorial group that meets three to four times a year and engages in various long-term projects, including projects funded by the European Commission and the World Health Organization.

- **Report of Activities 2009**

The Ethics Working Party held 3 Working Party meetings in 2009: in January, May and September. In 2009, the EWP organised or was involved in the organisation of the following workshops/conferences:

- Workshop held in January 2009 in Basle, Switzerland, on “Complex Cases for Research Ethics Committees Involving Research with Geriatric Patients”
- Training day held in April 2009 at the Headquarters of EORTC, Brussels, on ‘The Principles of GCP’ for experienced investigators (which will be repeated in 2010)
- Workshop held in June 2009 in Brussels on the Patient Partner Programme
- Workshops held in July 2009 in Brussels and in September 2009 in London on the Road Map Initiative for Clinical Research in Europe
- Workshop organised by the “Sensible Guidelines for Clinical Trials” Group in Oxford in September 2009
- 2 Training days held in September 2009 on ‘The Principles of GCP’ for 2 Phase I CROs in Germany, commissioned by Grünenthal
- Programme for the EFGCP Annual Conference 2010 in Brussels
- Workshop organised by the European Commission’s DG Research on Impact of the CTD on academic clinical research in November in Brussels

The following activities were progressed by the EWP in 2009:

- Update on the EWP Report on Ethics Committees in Europe
- Publication on the EFGCP Website of the “Guidance for auditing quality systems of independent research ethics committees in Europe”
- Production of the Final Report on the ICREL Project on the Impact of the Clinical Trials Directive on Research in Europe
- Establishment of a Research Integrity Sub-Group with the remit to take forward the 11 conclusions reached at the EFGCP 2009 Annual Conference and to produce a report for submission to the Second World Conference on Research Integrity
- Liaison with the UK National Research Ethics Service regarding
 1. the financial aspects of children’s research
 2. the status and nature of quora and the conduct of meetings of research ethics committees across Europe
 3. a comparison between REC procedures in Europe and those in the USA, Canada, Brazil, Japan, China, India and Australia
- Early liaison with Synergy, a major Russian CRO, on behalf of the Russian Federal Service on Surveillance in Healthcare and Social Development, for the production of a GCP training programme for investigators in Russia

- Representation of EFGCP in the EUDRACT Technology Implementation Group and its Joint Operations Group at the EMEA and the production of a report on The Reasons Why Research Ethics Committees Turn Down Submissions of Projects for Ethical Review
- Representation on the European Consortium of Biobanks Initiative (BBMRI)
- Creation of a Subgroup to perform the Work Package 7b activities in the IMI-funded PharmaTrain project
- Support to preparation of three Expressions of Interests to large FP7-funded scientific projects that need ethical oversight.
- Support to the creation of the programme for 3 workshops within the Road Map Initiative for Clinical Research in Europe" on risk-based approach, ethical review and pharmacovigilance.
- Support to FEAM, the Federation of European Academies of Medicine, for their response to the Clinical trials Consultation of the European Commission.
- Liaison with Wales Universities on an FP7 initiative to investigate ethics capacity-building methodology
- **Planned Activities in 2010**
 - 25 January 2010 meeting, Residence Palace, Brussels, to coincide with the EFGCP annual conference
 - Update of the EWP report on research ethics committees in Europe and completion of the UK NRES sponsored comparison between REC function in Europe and the rest of the World.
 - Presentation of the report of the Research Integrity Sub-Group at the Second World Conference on Research Integrity to be held in Singapore in July 2010
 - Development of the relationship recently established with the Russian responsible authority
 - Further development of a GCP training course for investigators and senior site staff
 - Further workshops on Difficult Cases for RECs and sponsors, concentrating on paediatric and geriatric cases
 - Organisation of the Final Workshop of the Road Map Initiative for Clinical Research in Europe on 17 March 2010 in Brussels
 - Creation of the ethical topics syllabus and the concept for ethical oversight of the IMI project "PharmaTrain"
 - Support of preparation of the full proposal for the MAGIC project.
 - Support to two more PatientPartner Workshops
 - Support to the programme development for the EFGCP Annual Conference 2011
 - Preparation of a workshop together with the Paediatric and the Geriatric Working Party as well as EUCROF on Ethical Aspects of clinical trials in populations at both ends of life in April 2010

GERIATRIC MEDICINES WORKING PARTY (GMWP)

- **17 Members**
- **Co-Chair:** Prof. Jean-Marc Husson, European Diploma in Pharmaceutical Medicine/Eudipharm, FR
Co-chair: Dr Florian von Raison, Merck Serono SA, Geneva, CH
- **Aim:** The EFGCP Geriatric Medicines Working Party is focused on developing three major areas of concerns regarding medicines for Europe's increasing elderly populations:
 1. A society concern: the present and future healthcare of elderly populations;
 2. A medical concern: the need for appropriately studied and labelled medicines, with particular attention to avoiding iatrogenic problems;
 3. An ethical concern: ensuring appropriate healthcare and research protections for Europe's elderly populations.
- **Report of Activities for 2009**

- In January 2009, the GMWP proposed together with AREC, the UK Association of Research Ethic Committee, a one-day workshop to discuss difficult cases for ethic committees. This workshop was held in Basel, Switzerland and hosted at the Swiss Academy for Medical Science and brought together around 25 attendees from various ethic committees, researchers and experts from academic centers and from pharmaceutical companies' drug development experts.
- In November 2009, the GMWP organized a two-day Workshop in Brussels, Residency Palace with the title: "The challenge of an aging population for medical research: Is Europe ready to cope" - chairpersons, Jean-Marc Husson and Florian von Raison.

The workshop brought together around fifty experts from the fields of clinical research, academia, health authorities, ethics, patients associations and the pharmaceutical industry to debate this question. The output of this meeting will be a common statement and text: "Ethical considerations: a proposal for older people in medical research" drafted by Jean-Marie Vetel and François Hirsch. This text could be signed by the attendees and send to appropriate stakeholders like European Commission, EMEA etc.

- The GWMP continued as well to support the validation of the decision making capacity evaluation tool for European languages and use. A validation in French and English are ongoing under the lead of two GMWP members, Laurence Hugenot-Diener, Paris and Mike Bone from Newcastle.

- **Planned Activities in 2010**

- The follow-up of the November workshop will include the finalization of the ethic statement and its appropriate diffusion to ensure that awareness for stakeholder is increased in addition to existing initiatives from other parties.

In order to strengthen the efforts and to create and use potential synergies, the GMWP will use the experience acquired in Europe by the pediatrics field, as for this population a similar effort was done in the past and these initiatives were very successful. As a first step is planed common EFGCP-EUCROF workshop in spring on shared ethical issues in paediatric and geriatric clinical trials to be held in Brussels.

- GMWP will maintain its' focus on improvement of the decision-making process and informed consent in this older population. The support of the validation of the tool of other languages is envisaged.

The usual process of information and consent appreciation needs to be completed by adapted tools and communication for elderly ensuring the full and mutual understanding.

PATIENTS' ROADMAP TO TREATMENT WORKING PARTY (PRTT)

- **34 Members and 15 affiliated members (2008 figures)**
- **Co-Chair:** Dr. Ingrid Klingmann, Pharmaplex, BE
Co-Chair: Mr. Ysbrand Poortman, EGAN, NL
- **Aim:** EFGCP and EGAN both promote Good Clinical Practice in clinical research and underpin the need for more patient involvement and high quality standards in all stages of biomedical research in Europe and beyond. Both organisations promote collaboration of all parties involved and believe that their combined efforts can better support the important role patient organisations can play in the medicine development process.

VISION

To strengthen patients' capacities to impact partnering in the medical research and development process aiming for faster access to effective and safe new treatments.

MISSION

To streamline the drug-development-centered activities of both organisations and to strengthen the potential of patient organisations in their contribution to the European research effort leading to faster development of effective and safe new treatments by providing information, know-how, skills, opportunities for exchange of information and funding for patient organisations.

- **Report of Activities 2008& Planned Activities in 2009**

- This common EGAN/EFGCP Working Party started 2009 with the participation in an EGAN multi roundtable conference for 35 EGAN members in different CEE countries on January 24 and 25 in Prague, just before the EFGCP annual Conference 2009. EFGCP presented its mission, vision and organisation as well as the EGAN/EFGCP collaboration in the Patients' Roadmap to Treatment Working Party and in the PatientPartner Project. These topics created great interest and many CEE-specific suggestions were made how patients could participate more actively in the development of new treatments and which hurdles need to be overcome. The Working Party's activities were welcomed and commitment was expressed by many different participants to support the WP's activities.
- The PRTT WP's major topic in 2009 was the support for the PatientPartner project. The WP helped with the development of the strategy, structure and content for the central and the 3 regional workshops supposed to elaborate and collect the needs, hurdles and options for patient organisations to increase their involvement in the development of new treatments in Europe. The starting central and two of the three regional workshops revealed many interesting results and the consequences of this process will be discussed at the final workshop in September 2010 for the ultimate conclusions of the PatientPartner Project.
- One of the outcomes of the CEE Workshop would be the task for the PRTT WP to assemble a sub-group of stakeholders from CEE countries to develop the syllabus for patient organisations training in Patient Organisations' involvement in new drug development.
- The PRTT WP had been very intensively involved in the Work Package "Training of Patient Organisations" of a large pan-European consortium of academic organizations and pharmaceutical companies in the IMI Call "Integrated Medicines Development". Unfortunately, the project was not awarded to anybody but the IMI Board is considering releasing a new call in 2010 on training of patient organisations. The PRTT WP has suggested some ideas to the IMI Board that could be considered in such a call. The focus of this proposal was on ideas of a "Virtual Patient Academy" that would enable patients from all over Europe to get access to training whenever and wherever they are able to take it. In case such a call would be released the PRTT WP would be in a good position to create a consortium of relevant stakeholders and to suggest a very important proposal as brainstorming on this topic has well progressed.
- Last but not least the development of new books on experiences of patients and patient organisations with the development of new treatments has well progressed.
A major challenge for the WP in 2010 will be the recruitment of more active members.

EFGCP In-house GCP Training Course for Experienced Researchers

Since its inauguration in 1993, part of the mission of the European Forum for Good Clinical Practice has been to develop education for and awareness of high ethical standards in clinical research and to facilitate knowledge transfer across sectors and disciplines. Pursuing this objective, the EFGCP has developed its own GCP Training Course for the experienced researcher. This offers an intensive one-day interactive programme that can be tailored to meet the needs of different groups involved in clinical research. The core of the course is devoted to the practical details that must be in place if a

clinical trial is to be conducted to GCP standards, but the history and fundamental principles of GCP are also covered, as is what to do if things go wrong. This GCP Training Course is provided by members of the EFGCP who are recognised experts in the relevant specific fields.

EORTC-EFGCP In-House GCP Training Course for Investigators EORTC Headquarters, Brussels, 24 April 2009

Five years ago, the conduct of clinical trials according to Good Clinical Practice (GCP) principles was introduced as a European Union regulatory requirement by the Clinical Trial Directive 2001/20/EC. However, despite overall commitment and best intentions to apply these requirements in clinical trials, monitoring, audits and inspections regularly find complexity and lack of harmonization of varying levels of severity. This indicated a need for those involved in the conduct of clinical trials in Europe to share their experiences with this clinical trial directive.

To further promote awareness about the current legal framework, the European Forum for Good Clinical Practice (EFGCP) in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) Headquarters took the initiative to develop a one day interactive investigator training course on GCP in clinical trials. This course, "EFGCP-EORTC interactive workshop on GCP: 5 Years Experience with the EU Clinical Trials Directive and its Implications on Your Clinical Research Practice", was held for the first time on 24 April 2009 at EORTC Headquarters in Brussels.

The topics covered in this course included GCP principles, set-up of a clinical trial at the investigative site, GCP compliance in document management, involving patients in clinical trials, critical elements of conducting clinical trials, what happens when things go wrong, and EudraVigilance - safety reporting of investigational medicinal products. The EFGCP faculty for the preparation of all course material and the workshop included Dr. Ingrid Klingmann, Expert in Drug Development Planning and Site Management Support, Pharmaplex bvba, Brussels, Belgium, Dr. Frank Wells, Expert in Misconduct and Fraud in Clinical Research, Ipswich, United Kingdom, Genevieve Decoster, ISO9000 Lead Auditor, IT & GCP Consulting sprl, Crupet, Belgium, and Prof. JanHasker Jonkman, Professor in Quality Management in Drug Research and Manufacturing, University of Groningen, The Netherlands.

The GCP Course was accredited by the Accreditation Council of Oncology in Europe (ACOE) and granted 6 European CME credits. It was attended by 60 participants representing six countries and 24 institutions in Europe.

2 other GCP training courses were successfully provided on-site in Germany for 2 CROs.

A list of 'à la carte' training modules including a 3-day programme for Investigators-initiated Clinical trials should be soon available to organisations and companies who seek to offer their members or employees high-quality interactive courses that will bring real added value to their knowledge and professional achievements. An initiative with Russia is under discussion for possible training in 2010.

ROADMAP INITIATIVE FOR CLINICAL RESEARCH IN EUROPE

This Initiative brings together representatives of academic and not-for-profit organisations who have been involved in EU-funded projects to investigate different aspects of the clinical trials environment in Europe following implementation of the Clinical Trials Directive (DIR 2001/20/EC) and/or to promote academic clinical trials.

The various groups first came together in October 2008 at a meeting organised by the CLINT project to discuss the main recommendations arising from each project with a view to developing joint recommendations to the EU. Having identified a number of topics of common concern, the partners agreed to collaborate in exploring these issues further through a series of stakeholder workshops aimed at developing a body of recommendations to feed into a review of DIR 2001/20/EC planned by the European institutions in 2010. The series of workshops aims to bring together all of the relevant stakeholders (commercial and non-commercial sponsors, investigators, ethics committees, competent authorities and patients) and the outcomes of the workshop will culminate in a Stakeholder Conference in March 2010 to which representatives of DG SANCO, DG Enterprise and DG Research will be invited to participate.

The main goal of the Road Map Initiative is to work towards suggestions for improvement in potential new legislation with the aim of facilitating the performance of clinical research for the benefit of patients and to increase the competitiveness of clinical research on a European level. In order to be heard it is essential to have a united academic voice, which was missing during the development of the Directive. The Initiative is open to representatives from all stakeholder groups with an interest in supporting the development of broadly agreed elements for improved clinical trials legislation.

Key partners in this initiative have undertaken to take the lead in organising one or more of the workshops aimed at exploring possible solutions to the most critical obstacles to clinical trials in Europe:

Schedule of workshops:

Date	Venue	Topic	Organised by
7th July 2009	Brussels	Single Clinical Trial Approval (CTA) Process	EFGCP
21 September 2009	London	Co-sponsorship and contractual issues	CLINT/EBMT
18 – 19 January 2009	Barcelona	Risk-based approach and Ethics Committees	ECRIN
8th February 2010	Brussels	Pharmacovigilance	EORTC
17 March 2010	Brussels	Stakeholder Conference with EU	EFGCP

Possible solutions identified for exploration with stakeholders through these workshops:

- To require only one Clinical Trials Authorisation (CTA) irrespective of the numbers of participating nations, either by the development of a single CTA application across Europe or the mutual recognition of authorisations by Competent Authorities
- To simplify and harmonise the procedures for clinical trial approval (e.g. the EudraCT forms as a single set of forms to be completed) and safety reporting (Eudravigilance and reporting rules)
- To define better and harmonise the roles of the ethics committees (achieve the so-called single-opinion) and of the competent authorities
- To adopt a risk-based approach: adaptation of the regulatory requirements considering the risk associated with the trial with regard to the safety reporting (e.g. limited safety reporting for commercially approved drugs), data monitoring, insurance, application dossiers, substantial amendments, free-of-charge supply of drug (e.g. not in case of market approval)
- To allow co-sponsorship in the case of multinational trial with the aim of facilitating collaboration between research groups

- To better define terms and concepts (IMP, interventional study, substantial amendment, etc.)
- To increase public financial support to investigator-led clinical trials
- To harmonise insurances requirements e.g. uniform costs per country, minimum and maximum indemnity payments, total duration of coverage, time to permit claims etc

Collaborating organisations and projects behind this initiative:

CLINT: Facilitating international prospective clinical trials in stem cell transplantation (EU funded project)

EBMT: European Group for Blood and Marrow Transplantation

ECRIN: European Clinical Research Infrastructures Network

EFGCP: European Forum for Good Clinical Practice

EORTC: European Organisation for Research and Treatment of Cancer

ELN: European Leukaemia Net (EU funded project)

ICREL: Impact on Clinical Research of European Legislation (EU funded project – ended in Jan 2009)

UCLAN: University of Central Lancashire, Centre for Professional Ethics

WEB

Since the launch of the new EFGCP website in September 2007, the number of visits average has kept increasing. The EFGCP Board and Bureau strive to make it a useful and user-friendly tool for any visitor looking for information about ethics and clinical research.

The statistics give the following information:

Year	From April 2008	in 2009	
Visits	18,861	25,387	This is the number of individual visits
Absolute Unique Visitors	9,054	12,596	All visits from the same user for the entire year are aggregated so that they are counted as a single absolute unique visitor, regardless of how many different days they visited the site and how many times they visited the site on each day
Page Views	76,227	89,200	
Average Page Views	4.04	3.51	
Time on Site	00:03:28	00:03:15	
New Visits	47.26%	46.93%	

(source: Google analytics)

In 2009, the most visited pages (letting alone the Homepage) were:

1. The EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union
2. The ICREL project page
3. The EFGCP Publications page, very closely followed by the GCP Training page.

A lot of efforts were made in 2009 to clean and update the EFGCP distribution list which currently counts more than 7,000 contacts.

PUBLICATIONS

EFGCP Report on '*The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union*'

This report originally published in 2006 was prepared by the EFGCP Ethics Working Party sub-group on Ethics Committees which has then tackled the challenge of identifying what over thirty aspects of the ethical review process is for each member state, plus Norway and Switzerland, and has brought this information together. The report rapidly became an invaluable reference document for any company, academic department or contract research organisation wishing to conduct clinical research anywhere in Europe with more than 1,500 copies distributed.

The national sections of the report are updated each year and made publicly available on the EFGCP website. The latest update of national flowcharts was performed in March 2009.

EFGCP GUIDELINES

Since its creation, EFGCP is dedicated to bringing leading publications on GCP in Europe and abroad.

In 2009, the Ethics Working Party subgroup on Quality Assurance prepare the **Guidance to Research Ethics Committees on Initial Facility Assessment**, which will be available in 2010 on the EFGCP website and provided to all EFGCP members.

EFGCP NEWSLETTER

In 2009, EFGCP kept a biannual periodicity for the publication of the *EFGCP News* with a 16-pages issue in Spring and in Autumn. The newsletter includes the meetings reports as well as updates on all EFGCP activities and initiatives the association is involved in or undertaken by partner organisations. The *EFGCP News* goes automatically to all EFGCP members and to a selection of +/- 1,000 other recipients at an international level. It is also displayed at EFGCP events and other conferences organised by partner organisations, and available on the website.

FP7 PROJECTS*

* EU-funded Framework Programmes for research and technology development

PROJECTS CONDUCTED DURING 2009

ICREL – Impact on Clinical Research of European Legislation

ICREL was a one-year project financed by the European 7th Framework Programme coordinated by EFGCP. Its aim was to measure and analyse the direct and indirect impact of the Clinical Trials Directive 2001/20/EC and related legislations in the EU on all categories of clinical research and on the

different stakeholders: commercial and non-commercial sponsors, ethics committees and competent authorities. In order to reach a maximum of information, a survey was conducted.

The first results of this survey were presented and discussed during a conference in Brussels on 2 December 2008. The conclusions of the meeting were to prepare the final report to the European Commission, including the recommendations for legislative environment changes. The results and conclusions were immediately published publicly on the ICREL website in 2009 and disseminated in the EFGCP News.

As the 1st FP7 Project reporting, EFGCP gained knowledge and expertise with the FP7 administrative rules and financial guidelines. In late 2009, EFGCP was informed that the European Commission had decided to carry out a financial audit of the cost statement submitted by EFGCP. On 22 & 23 December 2009, a financial audit was conducted by KPMG at the EFGCP Office. The resulting report is expected in early 2010.

The Project partners were:

- European Forum for Good Clinical Practice (EFGCP) – Coordinator
- European Organisation for Research and Treatment of Cancer (EORTC),
- French Institute of Health and Medical Research (Inserm),
- Hospital Clinic i Provincial Barcelona,
- Ethics Committee of the Medical University Vienna

Website: www.efgcp.be/ICREL

PatientPartner (PPCR) – Identifying the needs and possibilities for Patients Partnering in Clinical Research

The aim of this FP7 3-year Coordination Action is to identify the patients' needs for partnership in the clinical trials context and lead to both a well-organised and sustainable communication platform and guidelines to enable the mutual beneficial interactions between patients and clinical trials professionals. After carrying out a large survey and interviews addressing patients (-organisations) in order to identify preliminary needs in the clinical trials context from a patients' perspective, subsequent workshops attended by patients (and patient organisations), researchers and scientists, biopharmaceutical companies, regulators and other stakeholders in the clinical trials context were organised by EFGCP in Brussels (Central Start-up Workshop-, London (North-Western Regional Workshop), and Budapest (Central-Eastern Regional Workshop) in 2009. The Southern Regional Workshop and Final Conference are planned to take place respectively in March and September 2010.

The conclusions from the interviews, literature studies and best practices will be challenged to draw 'European' viewpoints and consensus. The establishment of a European Network of Patients partnering for Clinical Research (EN-PCR) is also planned. Initially, EN-PCR will be responsible for addressing the high priority issues in this project: paediatric clinical trials, patient registries and biobanks, the Innovative Medicines Initiative (IMI) and ethical issues. Later on, EN-PCR will guarantee the sustainability of this project, being a permanent structure with a bi-directional purpose, both empowering patients and functioning as a one-stop shop for academic and biopharmaceutical research. Further dissemination of the project results will be achieved by a Patient Guide for patient organisations, an Investigator Guide for organisers and sponsors of clinical trials, a List of Recommendations for regulators and a thematic

website. The consortium will provide continued support to both EN-PCR and the PatientPartner website after this Coordination Action has ended.

This project is implemented by key European and national patient network organisations and EFGCP. It concurrently supports patient-centred clinical research and European biopharmaceutical competitiveness.

Project partners:

- Vereniging Samenwerkende Ouder- en Patiëntenorganisaties betrokken bij erfelijkheidsvraagstukken (VSOP) – Coordinator
- European Forum for Good Clinical Practice (EFGCP)
- European Genetic Alliances' Network (EGAN)
- Genetic Interest Group (GIG)

Website: www.patientpartner-europe.eu

Innovative Medicines Initiative (IMI)

Objectives

IMI's overall goal is to reinvigorate the biopharmaceutical sector in Europe. To reach this objective, a unique collaboration within the pharmaceutical sector will be implemented through the IMI: for the first time, competitor pharmaceutical companies will collaborate to find solutions in order to overcome the research bottlenecks in the drug development process.

The main challenges are:

- Industrial: Insufficient R&D investment
- Scientific: Technological complexity
- At European level: Research in Europe is fragmented and tends to be located elsewhere.

To address these challenges, IMI will harness the know-how and expertise available across Europe's biopharmaceutical sector, by pooling competencies and resources from the public and the private domain. The research activities, to be supported under the IMI, will be open to all research actors, provided that they are performed within Europe.

Expected effects

IMI is expected to make Europe more attractive for biopharmaceutical R&D investments and boost the competitiveness of European life science R&D. By directly addressing the challenges facing the biopharmaceutical sector in Europe, IMI has the potential to:

- Modernise the development of medicines.
- Expand European expertise and know-how in new technologies to attract bio-medical R&D investment to Europe.
- Anchor R&D jobs in Europe and reverse the brain drain.
- Enhance Europe's economy by strengthening the competitive position of smaller companies, enabling them to collaborate with a multitude of stakeholders.

EFGCP is a partner of the consortium which won the Call 16 on Pharmaceutical medicine training programme - PharmaTrain (duration 5 years) and is coordinating the Ethical Issues Task Force, composed of members of the Ethics Working Party.

PROJECT APPLIED FOR DURING 2009

MAGIC Project on Hormonal homeostasis in human development, in Adult, Menopause and Aging to Increase lifespan: effects on Cardiovascular diseases

This Collaborative Project - Small or medium-scale focused research project has passed the 1st review by the European Commission and should submit in early 2010 a full project proposal where EFGCP will be responsible for the Ethics Work Package.

SCHEDULED UPCOMING EVENTS IN 2010-2011

EFGCP CONFERENCES

The EFGCP Annual Conference 2010 on Aspects of Personalised Medicine for Society – a Challenge Yet to be Met

In partnership with the Association of the British Pharmaceutical Industry (ABPI), the Belgian Association of Pharmaceutical Physicians (BeAPP), the Belgian College of Pharmaceutical Medicine (BCPM), Biologue, the German Pharmaceutical Industry Association (BPI), European Biopharmaceutical Enterprises (EBE), the European Clinical Research Infrastructures Network (ECRIN), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Genetic Alliances' Network (EGAN), the European Platform for Patients' Organisations, Science and Industry (EPPOSI), the European Association for Bioindustries (EuropaBio), the French Pharmaceutical Companies Association (LEEM), pharma.be, vfa bio and (media) Science/Business

Résidence Palace, Brussels, Belgium, 26 & 27 January 2010

Final Conference on Recommendations from the Roadmap Initiative for Clinical Research in Europe

To be organised by EFGCP on behalf of the Roadmap Initiative for Clinical Research in Europe

Diamant Centre, Brussels, 17 March 2010

EFGCP-EUCROFT 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

PatientPartner Southern European Regional Workshop on Defining the needs and means for more Partnership between Patients, Patient Organisations and Other Stakeholders in Clinical Trials

To be organised by EFGCP on behalf of PatientPartner

Barcelona, 24 & 25 March 2010

PatientPartner Final Conference

*To be organised by EFGCP on behalf of PatientPartner
Brussels, Belgium, September 2010*

Children's Medicines Working Party 6th Annual Conference

London, United Kingdom, 27 & 28 October 2010 (to be confirmed)

EFGCP Annual Conference 2011 on Certified GCP Training – Needs and Expectations

Budapest, Hungary, 1 & 2 February 2011

CONFERENCES IN PARTNERSHIP WITH EFGCP

Multidisciplinary Workshop on Risk Based Approach in Clinical Trials

*Organised by ECRIN on behalf of the Roadmap Initiative for Clinical Research in Europe
Hospital Clinic Barcelona, Spain, 18 January 2010*

Multidisciplinary Workshop on Research Ethics Committees and Ethical Review in Europe

*Organised by ECRIN on behalf of the Roadmap Initiative for Clinical Research in Europe
Hospital Clinic Barcelona, Spain, 19 January 2010*

Multidisciplinary Workshop on Towards A Better Future for Pharmacovigilance in Clinical Trials

*Organised by EORTC on behalf of the Roadmap Initiative for Clinical Research in Europe
EORTC Headquarters, Brussels, Belgium, 8 February 2010*

EFGCP MEETINGS

EFGCP Board Meetings

25 January 2010, Résidence Palace, Brussels

16 March 2010, EFGCP Office, Brussels

17 May 2010, EFGCP Office, Brussels

6 July 2010, EFGCP Office, Brussels

7 September 2010, EFGCP Office, Brussels

29 November 2010, EFGCP Office, Brussels

31 January 2011, Budapest, Hungary

EFGCP Annual General Assembly Meeting

26 January 2010, Brussels, Belgium

1 February 2011, Budapest, Hungary

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