



'where science and ethics meet'

ANNUAL REPORT 2008

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General Assembly

As usual, EFGCP organised its Annual General Meeting during its Annual Conference, at the end of the first Conference day on 29 January 2008 at the Résidence Palace. The minutes were sent to members and remain available at the EFGCP Secretariat.

Board

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

- 28 January 2008, Résidence Palace, Brussels, Belgium
- 17 March 2008, EFGCP Office, Brussels, Belgium
- 19 May 2008, EFGCP Office, Brussels, Belgium
- 7 July 2008, EFGCP Office, Brussels, Belgium
- 15 September 2008, EFGCP Office, Brussels, Belgium
- 1 December 2008, EFGCP Office, Brussels, Belgium

The EFGCP Board of Directors in 2008 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
Dr. Thierry Nebout	Board Member
Mr. Gerard J Marsat	Board Member

Bureau

The EFGCP Bureau is the organisational arm of the EFGCP responsible for all the operations of the association and its membership services. All the EFGCP events are also managed internally.

Its team is now composed of 3 employees, with the joining of Corinne Gaillard for the ICREL Project in 2008. Ms Gaillard will permanently work for EFGCP from 1 Jan. 09 as its Project Coordinator while Pauline Havelange will be promoted as Admin. & Finances Coordinator. EFGCP is striving to progressively adopt a professional structure adapted to its needs.

The office in Brussels is still shared with the European Platform for Patients' Organisations, Science & Industry (EPPOSI) within a sub-lease agreement. Another expression of interest to share office and personnel has been received and is being discussed for 2009.



**Ms. Fanny Senez,
Chief Operating
Officer**



**Ms. Pauline Havelange,
Admin. & Finances
Coordinator**



**Ms. Corinne Gaillard,
Projects Coordinator**

MEMBERSHIP IN 2008

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 2008, 187 members have joined EFGCP or renewed their membership, which represents an increase of 40 members compared to 2007.

Overview by Country

Country TOTAL	Country count TOTAL
Australia	1
Austria	4
Belgium	25
Bosnia and Herzegovina	1
Bulgaria	7
Croatia	2
Czech Republic	3
Denmark	6
France	16
Georgia	2
Germany	11
Greece	3
Hungary	3
India*	2
Ireland	5

Italy	3
Japan	1
Latvia	1
Norway	1
Poland	3
Romania	2
Russia	3
Serbia	5
Slovak Republic	1
South Africa*	2
Spain*	3
Sweden	5
Switzerland	14
The Netherlands	11
Ukraine	1
United Kingdom	32
United States of America	14
TOTAL	187

* new countries, compared with 2007

Overview by category

Profiles	2005	2006	2007
Academic	38	40	41
Biotech Industry	9	8	4
CRO	14	18	11
Ethics Committee	ND	5	3
Government/Regulatory	8	14	10
NGO	6	8	8
Patient Organisation	ND	1	4
Pharma Industry	50	50	47
Student	0	0	2
Other (Consultant, Editor...)	9	9	17

ND = Not Defined

2008 - Profiles	Nbr.
Academic Organisation	46
Biotech Industry	4
CRO Industry	16
Government/Regulatory Organisation	15
Non-governmental Organisation	18
Other	12
Patient Organisation	5
Pharmaceutical Industry	66
Retired Member	1
Student	4
TOTAL	187

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 are available to suit all types and sizes of organisations with solid benefits. The two first EFGCP corporate members are Crossover CRI and Pfizer.

Institutional Membership

EFGCP has decided in parallel to the Corporate Membership initiative to launch 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 Member in 2008 is the Institute of Clinical Research (ICR)

EVENTS 2008

EFGCP CONFERENCES

EFGCP Annual Conference 2008 on Safety in Clinical Trials – Are We in Jeopardy?

In partnership with the Association of the British Pharmaceutical Industry (ABPI), the Association of Clinical Research Professionals (ACRP), the Association of Research Ethics Committees (AREC), the Belgian College of Pharmaceutical Medicine (BCPM), the Drug Information Association (DIA), the European Aids Treatment Group (EATG), the European Clinical Research Infrastructures Network (ECRIN), the European Genetic Alliances' Network (EGAN), the European Platform for Patients' Organisations, Science and Industry (EPPOSI), the EuropaBio, the Regulatory Affairs Professionals Society (RAPS) and the Verband Forschender Arzneimittelhersteller (VFA)

Résidence Palace, Brussels, Belgium, 29-30 January 2008

Open meeting

Number of participants: 133

Report: available on the website & in the EFGCP News – Spring 08 Issue

EFGCP-AREC Workshop on Research Ethics Committee Difficult Cases

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

EFGCP Office, Brussels, Belgium, 26 February 2008

Open meeting

Number of participants: 11

Report: available on the website & in the EFGCP News – Spring 08 Issue

Workshop on How can Research Ethics Committees set and meet standards of good ethical practice – Standards, Accountability and Examples

*In partnership with the Bioethics Committee of the Polish Chamber of Physicians and Dentists
and the UK National Research Ethics Service (NRES)*

Polish Chamber of Physicians and Dentists, Warsaw, Poland, 8 April 2008

Meeting on invitation

Number of participants: 17

Report: available on the website & in the EFGCP News – Autumn 08 Issue

EFGCP Workshop on Training for Clinical Trials

23-24 September 2008, Medical Academy, Bishkek, Kyrgyzstan

Meeting on invitation

Report: available in 2009 in the EFGCP News

Workshop on Animal research & clinical studies: Ethical recommendations to ensure patients' safety in early drug development

With the support from the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Renaissance Hotel, Brussels, Belgium, 11 June 2008

Meeting on invitation

Number of participants: 36

Report: available on the website & in the EFGCP News – Autumn 08 Issue

**EFGCP-ITCC-DIA Conference on
*Meeting the Challenges of Paediatrics within Oncology Drug Treatment***

*In collaboration with the Innovative Therapies for Children with Cancer (ITCC)
and the Drug Information Association (DIA)*

Management Centre Europe, Brussels, Belgium, 25 November 2008

Open Meeting

Number of participants: 45

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

**EFGCP Children's Medicines Working Party 4th Annual Conference
EU & US Paediatric Legislation: What is Changing in Practice in Paediatric Drug
Treatment, Research & Development?**

Management Centre Europe, Brussels, Belgium, 26 November 2008

Open Meeting

Number of participants: 65

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

**A Conference on
Impact on Clinical Research of European Legislation – ICREL: Results & Discussion**

Diamant Centre, Brussels, Belgium, 2 December 2008

Open Meeting

Number of participants: 270

Report: available in 2009 on the website

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 six Working Parties are the following:

AUDIT WORKING PARTY (AWP)

- **36 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 2008**

The Audit Working Party (AWP) membership continues to increase by word of mouth. Most major companies are represented, together with many smaller organisations and independent consultants.

The AWP held three meetings in 2008, and plans to do the same in January, June and October 2009. Our first meeting of the year will be a discussion of risk management as related to quality practices. This will involve three members of European regulatory agencies, and aims to assist the development of an EMEA guideline on the subject.

The major activity of the AWP in 2008 was the production of a guideline on the role of the Quality Assurance Unit, in particular aimed at start-up QA units. There is no equivalent document in existence so this fills a definite need. This document has been released within the EFGCP, and is available from the website. It will be published in a future edition of "Pharmaceutical Medicine".

Early in 2008, a meeting was held on electronic medical records, and electronic data capture. It was very well received, and there was an open exchange of views across the floor.

Several surveys were conducted across the membership in 2008, and the resultant benchmarking data has been helpful to those who were involved.

Looking into the future, the WP will be considering position papers on various contentious issues for the industry, giving different sides of the discussion, and aiming to then present a consensus opinion of the best interpretation.

The AWP has developed informal links with the GCP Committee of the British Association of Research Quality Assurance. Our interests are similar in many ways, so exchange of information and ideas can be helpful to both groups.

As always, the AWP is driven by the interests and needs of its members, and the agendas of our meetings through 2009 will be focussed on areas of particular concern, raised by the membership.

CHILDREN'S MEDICINES WORKING PARTY

- **57 Members**

- **Chair:** Dr. Klaus Rose, FR. Hoffmann-La Roche, 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 2008**

The EFGCP Children's Medicines Working Party met face-to-face in Bruxelles in January 2008 at the side of the EFGCP Annual Meeting. We discussed the situation of the pediatric research and drug development in Europe & worldwide and decided that the Annual Meeting should take place

again in October with the focus on how the EU regulation is working in practice. Then DIA announced a pediatric conference for October, and ICDRA (International Conference of Drug Regulatory Authorities: www.icdra.ch & www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/index.html) a pediatric pre-meeting in September. The only potential meeting date that remained was late November 2008. The meeting was prepared by several teleconferences; furthermore, face-to-face meetings with many working party members took place on the side of other international meetings. The Working Party's Annual Meeting was organised back-to-back with a meeting on Pediatric Oncology as a follow-up to a first Pediatric Oncology conference in 2007. For both conferences, registration was initially low, but at the end both were well attended, and thanks to Tricia Fowler and feedback from the presenters we have now two full meeting reports on the EFPCP website. As few members of the working party go to Prague, we will perform a first TC in February / March 2009.

EDUCATION WORKING PARTY (EDWP)

- **7 Members**
- **Chair:** Mrs. Vesna Vujaklija, Veio Research, RS
- **Aim:** The specific role of Educational Working Party is to identify priority needs and primary challenges in the education and training of GCP among the various parties involved in preparing and carrying out clinical trials. As the multi-centre and multi-country clinical trials increase across Europe, there is a need to focus on the co-ordination and harmonisation of educational and training programs in GCP. At the same time, it is becoming more and more evident that different traditions in medical and scientific education across Europe need to be appreciated in developing GCP practices. The Education Working Party works toward developing cross-national understanding through 'train-the-trainer' programmes.
- **Report of Activities 2008**

None of the EdWP members took any initiative during the 2008, while Chairlady had to dedicate priority to her prime business activities, due to her move from Belgium to Serbia!

Nevertheless Balkan region was still focus of preliminary contacts and review of opportunities for 2009.

Croatia, as planned in 2008, deserves significant panel discussion, in the form of a workshop, for reflection on the most recent legal and regulatory changes. In cooperation with representatives from Croatia who are EFGCP attendees, EdWP will strive to realise this project in 2009.

Annual Conference 2009 in Prague will be the chance for gathering again individuals with interest for education.

Anticipated start of activities is February 2009.

ETHICS WORKING PARTY (EWP)

- **51 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 2008**

The Ethics Working Party held 3 Working Party meetings in 2008: in January, May and October.

In 2008, the EWP organised or was involved in the organisation of the following workshops/conferences:

- Workshop on 26 February 2008 in Brussels on "Research Ethics Committees Complex Cases – Learning from each other"
- Workshop on 8 April 2008 in Warsaw: "How can Research Ethics Committees Meet and document Standards of Good Ethical Practice?"
- Workshop on 11 June 2008 in Brussels: "Animal research and clinical studies: Ethical recommendations to ensure patients' safety in early drug development"
- Programme for the EFGCP Annual Conference 2009 in Prague

The following activities were progressed by the EWP in 2008:

- Update on the EWP Report on Ethics Committees in Europe
- Finalisation and release of the "Guidance for auditing quality systems of independent research ethics committees in Europe"
- Preparation and submission of comments to the new draft of the Declaration of Helsinki
- Preparation of the strategy for the Work Package "Training of Ethics Committees" within the Innovative Medicines Initiative call "Integrated Medicines Development"
- Support to ECRIN in preparation of an SOP for interaction with ethics committees
- Preparation of a programme for a workshop on informed consent in emergency situations to be held in 2009
- Representation of EFGCP in the EUDRACT Technology Implementation Group and its Joint Operations Group at the EMEA
- Preparation of a programme for a next workshop in Basel on "Research Ethics Committees Complex Cases – Learning from each other" in January 2009

- **Planned Activities in 2009**

- Ethics Working Party meeting: 26 January 2009, Diplomat Hotel, Prague, Czech Republic
- Need assessment and development of a training programme for ethics committees in drug development in the frame of the Innovative Medicines Initiative Programme on Integrated Medicines Development
- Update of the EWP report on ethics committees in Europe
- Workshop on informed consent in emergency situations in Cyprus
- Development of a GCP training course for investigators and senior site staff

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 2008**

Three WP-meetings during 2008 with the following major outcomes:

Decision-making evaluation: Improvement of the understanding and assessment of the decision-making capacity in the process of an informed consent for elderly in clinical trials seems to be worth to improve. The GMWP supports a pilot study run by LHD in Paris and MB in Newcastle to validate an existing US tool for major European languages like French and English.

Legal protection of older people and "Consultee" Concept: The GMWP analysed the data of 2007 survey about EC in EU done by the Ethic WP of the EFGCP. We identified that the concept and definition of Consultee or "personne de confiance" information varies across EU country. This has an impact on inclusion of older people in medical research and will lead to further evaluation of a better understanding of this concept.

A workshop to discuss difficult cases for ethic committees was decided to be done in January 2009 in Basel together with AREC, the UK Association of Research Ethic Committee.
- **Planned Activities in 2009**
 - Difficult cases one-day Workshop on 15 January in Basel hosted at the Swiss Academy for Medical Science together with AREC.
 - 2-day public Workshop in Brussels, Résidence Palace, on 23 and 24 April 2009 with the title : *"The challenge of aging population for medical research: 1/3 of the EU population will be more than 60 years of age in 50 years time"*

Different aspects of older people in medical research from regulatory, legal, ethic and others will be discussed. A potential draft for ethical guidance for medical research in older people is targeted as potential output of this meeting.
 - To continue to support the validation of the decision making capacity evaluation tool for Europe.

PATIENTS' ROADMAP TO TREATMENT WORKING PARTY (PRTT)

- **34 Members and 15 affiliated members**
- **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**

The Working Party held 4 meetings in 2008: in January, May, June and October

The PRTT WP progressed in the following activities in 2008:

- Production of a flyer to present the Working Party
- Development of membership
- Support to the EU-funded PatientPartner project
- Support to the development of the strategy for training of patient organisations in drug development in the frame of the Innovative Medicines Initiative Call "Integrated Medicines Development"
- Preparation of the programme for a patient information day (planned to be held in January 2009 in Prague, now delayed)
- Preparation of a programme for a Workshop "Patients – the Driving Force for Clinical Trials in Europe," planned to be held in June 2009
- Support to establishing a patient driven biomedical research virtual information centre

- **Planned Activities in 2009**

- Working Party meeting: 25 January 2009, Diplomat Hotel, Prague, Czech Republic
- Several Patient Information Days in different countries
- June Workshop (see above)
- Need assessment and training programme development for patient organisations in the frame of IMI's IMD call
- Support to programme development for PatientPartner workshops

WEBSITE

Since the launch of the new EFGCP website in September 2007, the number of visits and positive feedback greatly increased. New applications are now possible such as members' section, downloading of e-mails, on-line applications to membership.

2008 saw www.efgcp.be offer the possibility for conference participants to sign up online. Participants can also download the event presentations directly from the dedicated webpage after the meeting.

The statistical tool linked to the Website showed that 90,182 clicks were recorded in 2008.

A new tool has been set up in April 2008 to access more detailed statistics (Google Analytics). The visits recorded since then, expanded to the whole year, show that 76,227 pages were accessed on the Website. The difference is mostly due to automatic robots which are discarded from this new tool.

Year	2008	
Visits	18,861	This is the number of individual visits
Absolute Unique Visitors	9,054	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	
Average Page Views	4.04	
Time on Site	00:03:28	
New Visits	47.26%	

In 2008, 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 2 December 2008 ICREL conference presentations
3. The ICREL project and conference description

PUBLICATIONS

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

This report 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.

EFGCP then committed to have this report updated each year and publicly available on the EFGCP website. The latest update of national flowcharts was performed in March 2008 with the addition of Bulgaria, Croatia, Iceland and Serbia giving a new total of 31 countries.

The report is also cited in the new edition of Textbook in Pharmaceutical Medicine.

EFGCP GUIDELINES

Since its creation, EFGCP is dedicated to bringing leading publications on GCP in Europe and abroad. In 2008, 2 new guidelines were finalised:

The Role of the Quality Assurance Unit – by the EFGCP Audit Working Party
Available on the EFGCP website and in brochure format

Guidance for Auditing Quality Systems of Independent Ethics Committees in Europe – by the Subgroup on Quality Assurance of the Ethics Working Party
Available on the EFGCP website and soon in brochure format

EFGCP NEWSLETTER

In 2008 two larger issues of the *EFGCP News* were published in Spring and Autumn instead of the quarterly 8-page newsletters. The newsletter includes the meetings reports as well as updates on all EFGCP activities and initiatives the association took part in. The *EFGCP News* goes automatically to all EFGCP members and to a selection of +/- 900 other recipients at an international level. It is also displayed to EFGCP events and other conferences organised by partner organisations and available on the website.

FP6 & FP7 PROJECTS*

* Europe's Framework Programmes for research and technology development

PROJECTS CONDUCTED DURING 2008

ECRIN-TWG European Clinical Research Infrastructures Network – Translational Working Groups

The FP6-funded step (ECRIN-TWG) (October 2006-September 2008) was developed to enable provision of efficient support to sponsors in multinational studies, particularly interaction with ethics committees and competent authority, vigilance, monitoring and data management in pan-European studies. This is achieved through transnational working groups in charge of defining procedures and guidelines for multinational trials in the EU, with the local contribution of ECRIN correspondents embedded in each national co-ordination.

Six working parties perform in depth comparisons and prepare relevant documents. This knowledge is also translated into a training programme. The objective is to prepare ECRIN to provide integrated, 'one-stop shop' services to investigators and sponsors in multinational studies. In the meantime, ECRIN-TWG allowed extension to additional networks (Austria, Switzerland, EORTC).

It is now continued with ECRIN-PPI which started in March 2008 for a three-year period. During this step, the ECRIN network will change into a sustainable European institution, with a legal status of pan-European infrastructure, able to provide high-quality services to multinational clinical research.

Website: www.ecrin.org

Med-e PHV – Learning and Practicing Pharmacovigilance in the Mediterranean Countries of the EU

The Med-ePHV project intends to seek and develop an innovative approach to the E.U. pharmacovigilance practice by designing and implementing a pharmacovigilance co-operative e-

learning system specifically addressing the needs and profiles of health practitioners and patients of Southern Europe (Mediterranean countries). The system will allow to learn and to practice Adverse Drug Reactions notification at the edge of the pharmacovigilance systems.

EFGCP was mainly involved in the Dissemination Work Package to ensure communication is made about this initiative and the resulting tool at the European level and to all potentially interested stakeholders.

Website: www.medepbv.net

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 will be presented in the final report to the European Commission, together with the recommendations for legislative environment changes. The results and conclusions will be published and disseminated.

Project partners:

- 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

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. Moreover, this project will lead to both a well-organised and sustainable communication platform and guidelines to enable the mutual beneficial interactions between patients and clinical trials professionals.

This aim will be realised through:

1. Interviews, addressing patients (-organisations) that will identify preliminary needs in the clinical trials context from a patients' perspective. These data are complemented with literature reviews and descriptions of best practices. The combined outcomes will be accessible on a centralised web-based database.
2. Subsequent workshops addressing patients (and patient organisations), researchers and scientists, biopharmaceutical companies, regulators and other stakeholders in the clinical trials context. In these workshops – organized by the EFGCP partner –, the conclusions from the interviews, literature studies and best practices will be challenged to draw 'European'

viewpoints and consensus. On the specific website, attendees will be able to consult the outcomes from both the investigational phase and previous workshops.

3. The establishment of the European Network of Patients partnering for Clinical Research (EN-PCR). 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.
4. 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 a forum for Good Clinical Practice. 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

PROJECT APPLIED FOR DURING 2008

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 2 consortia which were respectively selected for the second round of submission of project proposals to Call 16 on **Pharmaceutical medicine training programme** (duration 5 years) and Call 17 on **Integrated medicines development training programme** (duration 5 years). The final answer is expected in March/April 2009.

Websites: http://imi.europa.eu/index_en.html

http://imi.europa.eu/docs/imi-scientific-priorities2008_en.pdf

2008 AOBs

EudraCT Joint Operational Group

EMA invited EFGCP to take part to the EudraCT JOG to ensure ethical input can be provided into the discussions onto CT regulations. Frank Wells is the official representative.

Representation of EFGCP at a number of external meetings and conferences was ensured by its Board members.

SCHEDULED UPCOMING EVENTS IN 2009-2010

EFGCP CONFERENCES

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

*Organised jointly by the Association of Research Ethics Committees (AREC)
and the EFGCP Ethics Working Party*

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

**The EFGCP Annual Conference 2009 on
Research Integrity: a European Perspective**

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

**EFGCP Ethics WP Workshop on
Complex Cases for Ethics Committees**

May 2009, Budapest, Hungary

**EFGCP Ethics WP Workshop on
Payment of Paediatric Participants**

May 2009, location to be determined

**EFGCP PRTT WP Conference on
Clinical Trials Topics of Interest to Patient Organisations
& their Involvement in Drug Development**

June 2009, Brussels, Belgium

**EFGCP Multi-sectorial Conference on
Follow-up to the ICREL Project:
A Single European CTA: a Dream or an Option?**

June 2009, Brussels, Belgium

EFGCP Children's Medicines Working Party Conference

Autumn 2009, Location to be determined

**EFGCP Ethics Workshop on
Complex Cases for Ethics Committees**

Autumn 2009, Montpellier, France

**EFGCP Annual Conference 2010 on
Personalised Medicines: a Last Resort?**

*26 & 27 January 2010, Brussels, Belgium
&*

Annual General Assembly Meeting

Tuesday 26 January 2010, Brussels, Belgium

NEW INITIATIVES FOR 2009

**EFGCP PRTT Working Party Info Day on
Basic Information to Patients**

EFGCP In-House GCP Training Course for Investigators

First course to be held on 24 April 2009
Interactive and practical training course for investigators to discuss
the fine line between correct conduct and misconduct

For any information:

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