where science and ethics meet

EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE

EFGCP REPORT OF ACTIVITIES 2016

STRUCTURE

General Assembly

EFGCP organised its Annual General Assembly Meeting as usual during its Annual Conference, on 29th February 2016 in Brussels, Belgium. The accounts and report of activities for 2015 were presented and the EFGCP Officers were provisionally relieved of their responsibility for the 2015 accounts until the final and closed version is presented at the AGM 2017.

Board

3 Board meetings were held:

- 29 February 2016, Crowne Plaza Le Palace Hotel, Brussels, Belgium
- 2 June 2016, EFGCP Offices, Brussels, Belgium
- 21 October 2016, EFGCP Offices, Brussels, Belgium

The EFGCP Board of Directors in 2016 was composed of the following members and officers:
(WP stands for Working Party)

Dr. Ingrid Klingmann	Chairman, Co-Chairman Medical Technology Stakeholder Alliance WP , EUPATI Network Leader
Mr. Gerald Van Roey	Vice-Chairman
Dr. Yves Geysels	Treasurer & Membership Officer
Dr. Florian von Raison	Secretary & Co-Chairman Geriatric Medicines Working Party
Prof. Dr. Jozef Glasa	Board Member & Ethics Officer
Prof. Olga Kubar	Board Member & Education Officer
Mr. Ysbrand Poortman	Board Member, Patients' Rights & Duties Officer, Co-Chairman Policy & Strategy WP
Mr. Paul Strickland	Chairman, Audit Working Party
Dr. Martine Delhinger-Kremer	Chairman Children's Medicines Working Party
Mr. Dimitrios Athanasiou	Co-Chairman Children's Medicines Working Party
Ms. Nicky Dodsworth	Chairman Education WP
Dr. Kim Champion	Board Member, Co-Chairman Ethics WP
Dr. Frank Wells	Board Member, Co-Chairman Ethics WP
Dr. Laurence Hugonot	Board Member & Co-Chairman Geriatric Medicines WP
Mr. Eric Klasen	Co-Chairman Medical Technology Stakeholder Alliance WP
Mr. Jean-Jacques Cassiman	Co-Chairman EFGCP-EGAN Patients' Roadmap to Treatment WP
Mr. Cees Smit	Co-Chairman EFGCP-EGAN Patients' Roadmap to Treatment WP
Dr. Alfredo Cesario	Co-Chairman Policy & Strategy WP
Dr. Helen Cadiou	Board Member
Dr. Anna Chioti	Board Member
Dr. Clara Heering	Board Member
Prof. Heinrich Klech	Board Member
Mr. Fabien Peuvrelle	Board Member

Secretariat

The EFGCP Secretariat is the organisational arm of EFGCP and is responsible for all the operational aspects of the association and its activities including membership services. All EFGCP events, trainings and projects continued to be managed internally in 2016.

As of the 31st of December 2016, the EFGCP team was composed of 4 members:

- Fanny Senez, Executive Director
- Ingrid Heyne, Project Coordinator / EUPATI Network Manager
- Philomène Bouchon, Communication & Membership Coordinator
- Sylvana Rodriguez, Admin & Events Assistant

The team also welcomed 2 trainees during the year.

The EFGCP office is located in the European district of Brussels. It went through full refurbishment in July 2014 and offers meeting capacity for up to 20 participants. It also hosts the secretariats of the PharmaTrain Federation and of EUFEMED.

MEMBERSHIP IN 2016

EFGCP Membership 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.

In 2016 EFGCP launched a membership development strategy to promote and increase membership (in all categories) starting with a registration campaign across the EFGCP working parties to ensure each member sitting in a working party is also an EFGCP member. Furthermore the secretariat personally recontacted people whose membership expired in 2015 and 2016 and who had not renewed.

Potential organisations that would benefit from joining EFGCP (medical societies, companies, academic institutions, etc) were also approached to better understand the current needs of these different audiences and what the role of EFGCP could be to interact better with its members and provide the right format of services. In the future, the work of the Policy and Strategy Working Party will help to achieve this goal at a larger strategic level for the organisation.

The team also developed a set of elevator pitches to present and promote EFGCP in a clear and pro-active manner. In 2017, the aim would be to continue such a recruitment strategy with the support of the new website which will also help to reposition EFGCP identity.

Individual Membership

In 2016, 142 members joined EFGCP or renewed their membership, in the continuity of 2015 with 141 members.

Overview by category

PROFILE	2012	2013	2014	2015	2016 (as of 31/12)
Academic Organisation	67	37	40	30	28
Association	4	2	3	2	2
Biotech Industry	5	5	4	6	8
Care Giver	/	/	/	/	/
Consultant	13	23	22	23	19
CRO Industry	34	30	22	17	17

Device Manufacturer	1	2	1	2	2
Ethics Committee	15	16	12	7	8
EU Project Consortium Member (non commercial/commercial)	/	/	/	/	/
European Regulatory Authority/Agency	/	2	2	1	/
Hospital Pharmacist/Lab Staff	/	/	1	/	/
HTA Commercial Stakeholder (non commercial/commercial)	/	/	/	/	/
Insurance Company	/	/	/	/	/
Medical Journalist	/	1	1	/	/
Medical Society	/	/	1	/	/
National Regulatory Authority/Agency	8	2	2	1	2
Non-Governmental Organisation	9	5	1	1	1
Nurse	1	3	2	1	2
Nutrition Company	/	/	/	/	/
Other	4	3	3	1	2
Patient Organisation/Advocate	7	7	9	5	4
Pharmaceutical Industry	58	47	38	38	38
Retired Member	9	9	8	6	8
Student	2	1	/	/	1
TOTAL	237	195	171	141	142

Overview by Country

COUNTRY	MEMBERS #
Austria	2
Belgium	24
Denmark	10
Estonia	1
France	11
Germany	18
Greece	3
Hungary	1
Ireland	1
Italy	8
Japan	1
Luxembourg	1
Poland	1
Portugal	1
Russia	2
Slovak Republic	1
Spain	3
Sweden	3
Switzerland	19
The Netherlands	10
United Kingdom	16
United States of America	4
22 Countries	142 Members

Corporate Membership

The launch of this new initiative in 2008 is a 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 and trade-associations 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 had been revised in 2009 to adapt to the economical conditions faced by all types and sizes of companies (bronze: 5,000 € / silver: 10,000 € / gold: 20,000 €).

In 2016 EFGCP has 4 Corporate Members: 1 Gold (Medtronic), 2 Silver (Novartis, UCB) and 1 Bronze (MedTech Europe).

Gold Member | Silver Members | Bronze Member

Institutional Membership

The Institutional Membership has been set up to formalise and promote EFGCP partnerships with other not for profit organisations (patient organisations, associations, universities, societies…) and encourage:

- Enhanced communication and interaction.
- Exchange of newsletters.
- Exchange of ideas, information and data regarding conferences.
- Networking between other organisations with which EFGCP and the institutional member are regularly in contact.

The number of institutional members is stable with 24 members.

Institutional members who joined or renewed their membership in 2016:

Thanks to the implementation of the 'organisation lists', the 24 Institutional and 4 Corporate Members represent 53 people on our membership list (27 Academic Organisations, 3 Associations, 8 Ethics Committees, 7 Patient Organisations, 8 Companies)

So the EFGCP MEMBERSHIP ACTIVE LIST is actually composed of
142 individual contacts + 45 institutional contacts + 8 corporate contacts = 195 member contacts

AFFILIATIONS

In 2016, EFGCP was a member of or ensured representation in the following organisations:

- European Platform for Patient Organisations, Science & Industry (EPPOSI).
- European Society of Association Executives (ESAE): EFGCP Executive Director Fanny Senez as Board Member.
- Federation of International Associations registered in Belgium (FAIB).
- PharmaTrain Federation.

EFGCP REPRESENTATION IN EXTERNAL EVENTS

In 2016, EFGCP was involved or represented in several events through the participation of Ingrid Klingmann as a member of the organizing committee or speaker and of Philomène Bouchon as an observer or active participant:

Ingrid Klingmann

- *Combacte CLIN-Net Annual Conference, Presentation, 25 January 2016, Grindelwald, Switzerland*
- *EUPATI ENP Switzerland Workshop, Presentation, 3 February 2016, Bern, Switzerland*
- *EUPATI, Webinar on Informed Consent, 21 March 2016*
- *EORTC Cancer Clinical Research Methodology Course for Patient Advocates, Presentation, 31 March 2016, Brussels, Belgium*
- *Clinical Trials in Central & Eastern Europe, 18 & 19 April 2016, Warsaw, Poland*
- *EUPATI: NLT/ENP Workshop, Presentation, 14 June 2016, Berlin, Germany*
- *CLINAM Conference (Nanotechnology), 29 June 2016, Basel, Switzerland*
- *EUCROF Conference, 18 October 2016, Prague, Czech Republic*
- *Ethical Workshop on difficult Cases in partnership with Swiss Ethics, Presentation, 7 November 2016, Luzern, Switzerland*
- *EUPATI: ENP Workshop, 25 November 2016, Lisbon, Portugal*
- *EUPATI : ENP Malta Workshops, 1 December 2016, La Valetta, Malta*
- *EUPATI Annual Conference 2016, Speaker and programme committee, 14 December 2016, Brussels, Belgium*

Philomène Bouchon:

- *European Health Parliament: Closing session, Observer, 29 June 2016, European Parliament, Brussels, Belgium*
- *European Brin Coucil Meeting: "Mental health and brain disorders: Ensuring joint EU and national level action", Observer, 13 July 2016, European Parliament, Brussels, Belgium*
- *Gastein Health Forum: Demographics & Diversity in Europe, active participation as Member of the Young Forum Gastein, 27th September-1st October 2016, Gastein, Austria*
- *MedTech Europe Workshop on E-health in Diabetes, 13th October 2016, Participant, European Parliament Esplanade, Brussels, Belgium*

EVENTS 2016

CONFERENCES & WORKSHOPS ORGANISED OR CO-ORGANISED BY EFGCP IN 2016

EFGCP Annual Conference 2016 on
Faster and Safer Paths to New Treatments with Medicines and Medical Devices
1 & 2 March 2016, Crowne Plaza Le Palace, Brussels, Belgium – 83 Participants

EFGCP Multi-Stakeholder Workshop & Discussion on
How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation?
Where do we currently stand with the implementation in different Member States
13 April 2016, MCE Conference Centre, Brussels, Belgium – 72 Participants

Joint EFGCP / DIA / EMA Better Medicines for Children Conference 2016 on
Optimisation of Drug Development for the Benefit of Children
10 & 11 October 2016, EMA Offices, London, United Kingdom – 137 Participants

EUPATI Graduation Ceremony
13 December 2016, Concert Noble, Brussels, Belgium – 170 Participants

EUPATI 2016 Conference – All Aboard to a Better Health Future
14 December 2016, The Square, Brussels, Belgium – 216 Participants

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 ethics, science, and regulation of clinical research in Europe and globally.

AUDIT WORKING PARTY (AWP)

- 74 on the distribution list. In 2016 the secretariat and AWP chair made a concerted effort to ensure all on the list were paying members of the EFGCP.
- Chair: Mr. Paul Strickland, Strickland Quality Assurance Ltd., UK.
- Aim: The Audit Working Party discusses GCP and regulatory issues in clinical research. Its primary focus is the work of the professional clinical trial auditor, with a view towards 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.
- Number & dates of meetings in 2016:

12 January 2016, 21 June 2016 and 25 October 2016

- Report of Activities 2016:

The AWP grew by 10 % over 2016. This is the sixth year of growth since reports have been compiled in this format.

A DKMA inspector accepted an invitation to address the group in January 2015.

The development of the Clinical Trial Regulation and organisational preparations for its implementation were discussed in detail in each meeting.

EFGCP comments on the ICH E6 addendum were contributed, collated and submitted by members of the AWP. Several comments were adopted.

A vast amount of information was shared between members between meetings. This covered development of regulatory viewpoints, inspection outputs, new and revised guidance and questions of interpretation and viewpoint.

Benchmarking is one of our greatest strengths – 12 individual benchmarking activities took place across the whole WP this year. This is a small decrease compared to last year.

The AWP already has inspection preparation material for training investigator site staff (predominantly). In 2016, the team completed material for an advanced GCP training course, for those already familiar with the subject. It is our hope that both these programmes will run in 2017. An approach was made to an Asian consortium of companies, but their initial interest did not lead to a sale.

UAT of the Union Database and Portal was arranged via the AWP

- Development against annual KPIs:
  1. Number of F2F meetings – 3, as specified
  2. Number of benchmarking activities: 12, a small change from 17 in 2015
  3. Membership increase of 10%
- Projects & Planned Activities in 2017:

  Closer liaison was proposed by the RQA to identify synergies and economies. This was discussed with the Board but not taken further.
- 2017 Meeting Dates & locations:

  23 February, 2017, Brussels, June 2017 TBD and October 2017 TBD

CHILDREN'S MEDICINES WORKING PARTY (CMWP)

- 20 members
- Chair: Dr. Martine Dehlinger-Kremer
- Co-Chair: Mr. Dimitrios Athanasiou
- Aim: Facilitates the discussion in Europe towards a broader public agreement on the needs for better medicines for children.

  Focuses on the development of an ethical and scientific framework for clinical research for children.

  EFGCP uses its traditional strength in consensus building in forming a coalition of core representatives from paediatricians & academia, regulatory authorities, patients' & parents' organisations, ethical committees and the research-friendly media on a European level
  Objectives: Development of safe and effective medicines for children
  (1) identifying issues and best practices in order to develop harmonized solutions related to the practices of paediatric research and clinical trial designs in a global context; (2) establishing and maintaining effective cooperation with European and International organizations, including policy makers, patient organizations, regulators, academic societies and professional organisations; and (3) developing and publishing recommendations in order to contribute ethically and scientifically sound development processes, research practices and increase access of children to effective and safe medicines.
- Number & dates of meetings in 2016:

9 meetings: 7 TC and 2 F2F, one in Brussels on 29/02/2016 and one in London on 12/10/2016

- Report of Activities 2016: please see below.
- Outputs (events, guidelines…):

'Joint DIA/EFGCP/EMA Better Medicines for Children Conference 2016 on Optimisation of Drug Development for the Benefit of Children', 10 & 11 October 2016 -- European Medicines Agency, London, United Kingdom – 128 participants.

Review of the document "Ethical Considerations for Clinical Trials on Medicinal products Conducted with Minors and submission of comments to EU Commission through Enpr-EMA in August 2016.

- Development against annual KPIs:

1. 'Joint DIA/EFGCP/EMA Better Medicines for Children Conference 2016 on Optimization of Drug Development for the Benefit of Children' (100% achieved)

2. Review of the document "Ethical Considerations for Clinical Trials on Medicinal products Conducted with Minors" and submission of comments to EU Commission through Enpr-EMA in August 2016. (100% achieved)

3. Assess hurdles and propose solutions for paediatric Clinical Research in Europe (100% achieved)

4. CMWP Response to EC Consultation on Paediatric Regulation (100% achieved)

- Projects & Planned Activities in 2017:

1. Organise Joint DIA/EFGCP/EMA Better Medicines for Children Conference in collaboration with EMA and DIA
2. WP 1: "Ethics" Review of the European Ethics Guideline for Paediatric Research, Consultation on the revision of "Ethical Considerations for Clinical Trials on Medicinal products Conducted with Minors".
3. WP2: *Assess hurdles and propose solutions for paediatric Clinical Research in Europe*
4. WP3: *"Review of 10 Years Paediatric Regulation"*

- 2017 Meeting Dates: 20 February: face-to-face meeting in Brussels

EDUCATION WORKING PARTY (EDWP)

- Approx. 6 active members
- Chair: Nicky Dodsworth, Premier Research, Reading, UK
- 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.
- Number & dates of meetings in 2016: We had one face-to-face meeting during 2016 – 29th January. There have been several telecons to address specific topics as well.
- Report of Activities 2016:
    1. EFGCP Annual Conference, 1st and 2nd March 2016: Faster and Safer Paths to New Treatments with Medicines and Medical Devices. Workshop 3: Chair: Oversight & Quality in Drug and Device Development
    2. Quality & Innovation in Complex Studies, June 2016, UCL, UK – planned but not delivered
    3. Advanced GCP Training co-developed with Audit Working Party: 2 Modules developed by EdWP
    4. GCP training for EORTC 9th June 2016, Brussels, with Ingrid and Nicky.
    5. Close working with the Medical Technology Working Party and Audit Working Party continues
- Projects & Planned Activities in 2017:
    1. EFGCP Annual Conference 2017: Meeting the Ethical Standards under the Clinical Trial Regulation, 21-22 February 2017. Workshop 3
    2. Quality & Innovation in Complex Studies, 12 June 2017, UCL, UK
    3. Updating GCP Training materials to include ICH GCP R2 updates
    4. GCP Refresher Training
- Development against annual KPIs:
    1. To hold at least 3 Education Working Party meetings per year, either face to face or by TCon. ACHIEVED 2/3
    2. To hold another Workshop in June at UCL facilities on Quality & Innovation in Complex Studies – planned but cancelled: NOT ACHIEVED
    3. To work with the Audit Working Party to develop Advanced GCP Training: ACHIEVED

- 2017 Meeting Dates:

  20th February 2017; May and October. Exact dates/locations are yet to be determined.

ETHICS WORKING PARTY (EWP)

New chairmanship and membership as of January 2017 after a blank 2016 year

- 15 Members
- Chair: Asst Prof Heather Sampson, Director of Clinical Research, Department of Family and Community Medicine at Toronto East General Hospital/University of Toronto
- Co-Chair: Mag. Andrea Heckenberg, Managing Director of the Ethics Committee of the Medical University of Vienna, Austria.
- 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.

  It is an international, multi-disciplinary, multi-sectorial group that meets two to three times a year and engages in various long-term projects, including projects that are externally funded and/or are sponsored by the European Commission and the World Health Organization.
- Number & dates of meetings in 2016: None
- Report of activities 2016: None
- Projects & Planned Activities in 2017

Next meeting: Monday, 20 February, 2017, 14:00 to 17:30 at Courtyard Marriott Hotel, Brussels.
The following topics have so far been identified as potential next EWP topics:
1. Ethical aspects of development and implementation of Lay Summaries as requested by the upcoming Clinical Trial Regulation
2. Multi-stakeholder consensus-building on ethical acceptance of clinical trial designs, especially in vulnerable populations
3. Ethical aspects of pregnancy in clinical trials and collection of biomedical research data in pregnant women
4. Recommendations and educational support for investigators to better manage the informed consent process
5. Adaptation of the Ethics Committee Report to the changes occurring in implementing the Clinical Trials Regulation in the EU Member States
6. Collection and dissemination of important information on ethical issues and developments
7. Impact of the recently released amended CIOMs ethical guidelines

GERIATRIC MEDICINES WORKING PARTY (GMWP)

- 6 active members
- Chair: Dr. Florian Von Raison, Novartis Pharma, CH.

  Co-chair: Dr. Laurence Hugonot-Diener, Broca Hospital APHP Paris, FR.
- Aim: The EFGCP Geriatric Medicines Working Party is focused on developing three major areas of concerns regarding medicines for Europe's increasing older populations:

  1. A society concern: the present and future healthcare of older populations.
  2. A medical concern: the need for appropriately studied and labeled medicines, with particular attention to avoiding iatrogenic problems.
  3. An ethical concern: ensuring appropriate healthcare and research protections for Europe's older populations.

The goal of the Geriatric Medicines Working Party is to examine issues in the development of geriatric medicines that include approaches taken by ethics committees, information on medicines and medical research provided to older patients, informed consent in older populations, new regulatory approaches, specific pharmaceutical formulations, and strategic approaches to educating society.

- Report of Activities for 2016

The GMWP published an ethical guidance document available as a dedicated chapter in a book released in 2016 edited by S. Stegemann *"Developing Drug Products in an aging population: Developing Drug of the older patient"* (Springer "Advances in the Pharmaceutical Science Series" Vol 24):
F. von Raison and L. Hugonot-Diener, on behalf of the Geriatric Medicine Working Party of the European Forum for Good Clinical Practice: Ethical considerations in performing clinical trials in and for older patients. (p117-128).

The GMWP had planned and announced a public workshop in Sep 2016 on ethical issues of older people in Clinical research in conjunction with new technology. This workshop was prepared to be done 1 day before the start of an international conference on Gerontotechnology in Nice. Despite intense advertising and collaboration with the congress chairs, the workshop had to be cancelled 1 month before the meeting as an insufficient number of attendees had registered.

Of note, the members of the GMWP were asked to join the EFCGP as member to be able to continue to benefit from the working party membership. A majority of members accepted this but some decided to leave the group.

- Number & dates of meetings in 2016: 1 face-to-face meeting per year along the annual EFGCP meeting. Regular, quarterly TC's, Emails, program Committees per TC etc.

- Outputs: Book chapter published in 2016: Developing Drug Products in Aging Society: From concept to prescribing

F. von Raison and L. Hugonot-Diener, on behalf of the Geriatric Medicine Working Party of the European Forum for Good Clinical Practice: *Ethical considerations in performing clinical trials in and for older patients*. (p117-128)

- Projects & Planned Activities in 2017:

1. We received an invitation from the DIA EuroMeeting in Glasgow.to speak in a session lead for the track "conducting clinical trials in special populations: older patients" (Thursday 30th March 2017 16:00-17:30)

2. The GMWP will organize a 90 min workshop as scientific symposium at the 26th European Stroke Conference, 24-26 May 2017 in Berlin
EFCGP Workshop entitled ***Ethical aspects of Clinical research in Geriatric Medicine***.

> 2.1/ Guidance synthesis: Medical Research for and with Older People in Europe: Proposed Ethical Guidance for Good Clinical Practice - Ethical Considerations: Laurence Hugonot-Diener *M.D. co-chairman of the EFGCP GWP and* Psychogeriatrician-CMRR Paris sud Hôpital BROCA-APHP
>
> 2.2/ The Geriatric Working Party of EMA Research in Geriatric & Regulation and Directives. Antonio Cherubini MD. Geriatrician in NRCA Istituto Nazionale di Ricovero e Cura per Anziani Department of Geriatric Medicine Ancona ITALY and EMA Geriatric Expert Group
>
> 2.3/ "Conducting clinical trials in older patients: Practical considerations"? Marie Laure Seux MD Geriatrician Department of Day Hospital –in charge of clinical research- CMRR Paris Sud, France

Another new area of activities was identified and need further refinement and feasibilities. The GMWP is considering developing a web-based publically available tool box addressing various elements of medical research in and for older people like relevant guidelines, ethical recommendations but also practical elements or examples (Informed consent form process, clinical study documents, etc)

The overall goal would be to promote and facilitate medical research in and for older people and allows this unique web portal. Today no comparable tool or web portal is available. The GMWP needs to develop the concept further and needs likely to seek a partner organization for that initiative.

- 2017 Meeting Dates:

Our 2017 meetings/ Telephone and face to face will be on 7th February or 13th February, from 4:00pm to 6:00 pm We have to elect/ renew the Chairman and co-chair, try to build a new workshop or to get new ideas.

EFGCP MEDICAL TECHNOLOGY STAKEHOLDER ALLIANCE (IN COLLABORATION WITH MEDTECH EUROPE)

- 50 members (on the distribution list)
- Chair: Eric Klasen, Medtronic, Switzerland
- Co-Chair: Ingrid Klingmann, EFGCP/Pharmaplex, Belgium
- Aim:
    1. to promote a high level of ethical and quality issues when setting standards for the rapidly developing medical technology sector (medical devices and in vitro diagnostics)
    2. to offer a platform for an exchange of views and opinions among stakeholders on topics of particular complexity and concern in the new EU Regulations on Medical Devices and in vitro diagnostics
    3. to collect views on good clinical practice, quality, ethical and other relevant issues as they pertain to medical technology and provide recommendations to policy-makers
- Number and dates of meetings in 2016:
    1. Working Party meetings on 14 January, 21 April, and 30 August and 3 November 2016
    2. EUDAMED Taskforce meetings on 9 June, 19 September, 29 November 2016
    3. EFGCP Annual Conference 2016 on Faster and Safer Paths to New Treatments with Medicines and Medical Devices, 1 & 2 March 2016, Crowne Plaza Le Palace, Brussels, Belgium
    4. Avicenna / EFGCP Meeting on 7 December 2016
- Outputs (events, guidelines…):

The EFGCP Medical Technology Alliance has reflected on its objectives for 2016-2017 in light of the ongoing debate on clinical evidence for medical devices and the need for continued stakeholder contributions to the future EU Medical Devices Regulation, especially the delegated and implemented acts and also contributing to the future EUDAMED database.

To ensure achieving continue meeting its goal of being a trusted partner of authorities, the EFGCP Medical Technology Alliance must be:

- A true multi-stakeholder group that reflects the views of patients, physicians, ethicists, industry, etc.
- A "catalytic group" that solves problems from various angles
- The place where ethical, legitimate and trustworthy forward thinking takes place.

- Projects and Planned Activities in 2017:
    1. The ‘Leiden Event’ is proposed to take place later in 2017. The set-up of the event is envisaged as an advisory committee workshop with academic, physician, patient and industry members who will participate by invitation-only. The goal of this roundtable will be to develop and publish guidelines and scientific article in partnership with University of Leiden (Professors Michel Ferrari and Adam Cohen)
    2. To keep working on the EUDAMED database and set up a survey to identify the needs of various stakeholders regarding the content of the database, focusing on the clinical section.
    3. To keep working on the delegated and implemented acts of the EU Medical Devices Regulation
- Future Meeting dates & location:

2 & 3 February 2017 at MedTech Offices (EUDAMED Taskforce & EFGCP Medical Technology Stakeholder Alliance meetings), mid-April / May 2017: exact date and location to be determined.

PATIENTS' ROADMAP TO TREATMENT WORKING PARTY (PRTT WP)

- 42 members (on the distribution list)
- Chair: Prof. Jean-Jacques Cassiman, KU Leuven
- Co-Chair: Mr. Cees Smit VSOP, NL.
- Aim: To strengthen patients' capacities to impact partnering in the medical research and development process aiming for faster access to effective and safe new treatments.
- Report of Activities 2016: Three meetings were held. The group discussed the topics that could be proposed during the planned hackathon, the possible locations and the sources of financial support. Contacts with different potential sponsors were made, without neither formal engagement nor refusal of the candidates. After reviewing the situation and the changing international context in which hackathons were organized, it was decided not to pursue this approach further and to fundamentally review what future activities PRTT might engage in.

  At the most recent meeting, everybody agreed that PRTT should renew itself: find a new name, a new identity and a new scope of actions. PRTT should be a problem solving body: a neutral platform where multi-stakeholder discussions can take place to tackle key biomedical issues.
  The group agreed that the working party should focus on the bigger picture and work as a facilitator organization providing, in collaboration with EPF, Eurordis and others, a platform to tackle concrete issues and conduct collaborative activities in other consortia.
  The main topic would be: "Think of different systems to develop new therapies. Make sure medicines and treatments are affordable". As proposed in the KCE reports new scenarios for the production of innovative treatments could be an interesting topic for PRTT. The WP could develop proposals on how to practically realize some of these scenarios.
  The new call for applications by IMI was briefly discussed. Ingrid Kligmann would gather more information on what could be a role for EFGCP or PRTT in this.
  The group also brainstormed on potential new names for the working party.
- Number & dates of meetings in 2016: 16th April, 26th October.
- Projects and Planned Activities in 2017: The chair, co-chair and the direction of EFGCP will discuss what the work program of the working party could be in view of the proposed topics and the possible involvement in the new IMI project.
- Future meeting dates & location: Will be decided ones the future role of PRTT will be clear.

POLICY & STRATEGY WORKING PARTY

- 7 members
- Chair: Alfredo Cesario, Fondazione Policlinico Universitario A. Gemelli - Università Cattolica del Sacro Cuore, Italy
- Co-Chair: Ysbrand Poortman, VSOP/EGAN, The Netherlands
- Aim: Policy and Strategy development for a sustainable EFGCP in the future.
- Report of Activities 2016: Subjects of elaboration were: the options for adapting EFGCP (the bundle of products and services) to the changing market needs, the balance in constituency (science, industry, patient organisations), channels of communication, revenue streams, others

  The WP also explored the options for functioning as a strategic council to the Board and proposed a structured roadmap relevant to other WPs to comment, adhere or implement.
- Number & dates of meetings in 2016: There were 3 face to face meetings: 23 August 2016, 30 November 2016, 2 meetings by conference call: 7 September 2016 and 24 October 2016.
- Outputs (events, guidelines...): A business model was set up and a proposal for an adapted vision and mission of the Forum was formulated for further deliberation.

- **Projects and Planned Activities in 2017:** The working party will communicate with the other EFGCP working parties to include their views in the conclusive discussions.
- **Future meeting dates & location:** 17 January 2017, others to be determined.

EFGCP TRAINING MODULES

In 2016, EFGCP organised six training sessions with 4 academic organisations (UZ Leuven, LIH, EORTC and IDF Münster) including two GCP training sessions and four GCP Refresher training sessions on more specific topics. As a recognized GCP training provider, EFGCP updated its offer and developed for 2017 an *EFGCP Portfolio of Training Courses* that offers seven different modules aimed for commercial or non commercial organisations staff (investigators, site personnel, etc).

TRAININGS ORGANISED OR CO-ORGANISED BY EFGCP IN 2016

1. EFGCP GCP Trainings

Interactive Training in Applied GCP for Investigators & Site Personnel on
The EU Clinical Trial Directive and Its Implications on Your Clinical Research Practice
19 February 2016, UZ Gasthuisberg, Leuven, Belgium - 117 Participants

Interactive Training in Applied GCP for Investigators & Site Personnel on
The EU Clinical Trial Directive and Its Implications on Your Clinical Research Practice
9 September 2016, UZ Gasthuisberg, Leuven, Belgium - 47 Participants

2. Refresher GCP Trainings

Refresher Interactive Training in Applied GCP for Investigators & Site Personnel
23 April 2016, Institut für Diabetesforschung, Münster, Germany - 18 Participants

Interactive Training in Applied GCP for Investigators & Site Personnel on
The EU Clinical Trial Directive and Its Implications on Your Clinical Research Practice
29 April 2016, UZ Gasthuisberg, Leuven, Belgium - 135 Participants

Good Clinical Practice Training on
How to write a Clinical Research Protocol for a Successful Project
28 May 2016, Centre Hospitalier Luxembourg (CHL) - 83 Participants

EFGCP-EORTC Interactive Training Course on
GCP in Clinical Research: The Sponsor's Perspective
9 June 2016, EORTC Headquarters, Brussels, Belgium - 71 Participants

WEB & SOCIAL MEDIA

EFGCP Website

The modernisation process of the EFGCP Website was initiated in 2016 and will be finalized in 2017 to provide new functionalities for members and working parties and improve the EFGCP on-line image.

In the meantime, the number of visits to the EFGCP website slightly decreased in 2016 with 9288 unique visitors throughout the year

	2014	2015	2016	
Visits	21,230	14,727	13,341	This is the number of individual visits
Absolute Unique Visitors	13,961	9,569	9,288	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	69,748	53,044	48,517	
Pages per Visit	3.29	3.60	3.26	
Time on Site	00:02:20	00:02:22	00:02:14	
New Visits	62.76%	61.91%	67.44%	

(source: Google analytics)

In 2016, 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.
2. The EFGCP Annual Conference 2016
3. The EFGCP Publications page

EFGCP Social Media Platforms

Twitter Account: @EFGCP

Active as of January 2015 (Annual Conference)
380 followers (as of 31/12/2016)
EFGCP gained 50% of followers within the past twelve months.

Who are EFGCP followers?

- Patient Organisations: EACR, EFNA, EFA, EATG, PACTeu, EPF, IPPOSI, ECPC, Patient View, Hepathitis Info, etc.
- EU Institutions: DG Health, Pietro de Matteis: president of the European Federalist Party, EU2016NL (the official Twitter account of the Netherlands presidency), Paolo Tomasi (EMA), EU eHealth, Horizon 2020
- National Institutions: NHS R&D Forum, NHR CRN NW London
- EU project: EUPATI, IMI, Active Healthy Ageing, IMI, IMI-Train
- Press & Media: BMJ, Euractiv Health, two journalists from Politico, Medical News Today, MedicRes
- Pharma & MedTech Companies: UCB, Premier research, Medtech Engine, Medeuromet, Leo Pharma, Lilly Pad EU,
- Brussels-based consultancies: B-M Brussels Health
- Trade associations: EGA, MedTech Europe, EAHP, EFPIA, Medicines for Europe (generics)
- CROs: SynteractHCR, AFCROs, DARQA
- Academia & Associations : EORTC, ICORG

Goals for 2017:

- The goal would be to be part of the 36% of Brussels-based organisations on Twitter with 500 to 2000 followers. (source: Cambre survey on Digital Associations)
- Currently EFGCP posts an average of three tweets a day. The objective would be to share an average of five tweets a day.

LinkedIn Company page EFGCP

209 Followers

EFGCP gained more than 60 followers within the past twelve months. As a Brussels-based organisation, EFGCP ranges currently in the average in terms of followers (54% of organisations in Brussels have an average of 200 followers on LinkedIn).

Goals for 2017:

- To make sure that EFGCP Members are following the organisation.
- To reach the 21% of organisations which have between 300 and 500 followers.

IMI PROJECTS*

* Innovative Medicines Initiative

PROJECTS CONDUCTED DURING 2016

IMI - EUPATI (2012-2017)

The 'European Patients' Academy on Therapeutic Innovation' (EUPATI) started its work on 1 February 2012 and hasl run for five years. This patient-led academy developed educational material, training courses and a public Internet library to educate patient representatives and the lay public about all processes involved in medicines development. Topics included personalised and predictive medicine, design and conduct of clinical trials, drug safety and risk/benefit assessment, pharmaco-economics as well as patient involvement in drug development. EUPATI provided educational material in seven European languages targeting twelve European countries.

The consortium, led by the European Patients' Forum, comprises of 33 leading pan-European patient organisations, academic and not-for profit organisations including EFGCP as well as EFPIA member companies. By leading Work Package 2, EFGCP was a member of the EUPATI Executive Board and provided the establishment and management of the EUPATI Network (1.289 Network members), the organisation of all EUPATI events, the establishment and management of the EUPATI National Platforms and was the host for EUPATI's Ethics Panel. EFGCP was also a member of the Work Packages 3, 4, 6 and 7 and was thus involved in nearly all other EUPATI activities.

2016, was an exciting year for EUPATI as it celebrated its first group of graduating Expert Patients, the EUPATI Fellows. The Fellows, consisting of almost 98 patients and patient representatives from 58 disease areas in 32 countries, will bring invaluable patient expertise and insight throughout the entire medicines development process. Their graduation marks not only the culmination of their studies but also of five years of effort by the EUPATI team. This is one of the most successful projects of the Innovative Medicines Initiative (IMI).

In December, 216 people attended the EUPATI Conference, "All aboard to a better health future!", in Brussels. Attendees heard from experts in the pharmaceutical industry, regulatory and academic fields of the growing influence of patients at all stages of medicine development. This ranges from helping identify unmet and under-met needs to input into product assessment and approval.

Great progress has been achieved in the 12 countries in 2016: There are now 14 EUPATI National Platforms (UK, Ireland, Spain, Italy, Austria, France, Malta, Luxembourg, Denmark, Portugal, Germany, Switzerland, Poland, Slovakia), and 6 further launches are expected in 2017 (Greece, Norway, Romania, Serbia, Sweden, Belgium).

In addition, 3 webinars were provided: "Informed consent for vulnerable populations" (107 participants), "Early collaboration – a recipe for solutions: drug development and treatment strategies may go hand in hand" (144 participants) and "Creating Trainings with the EUPATI Toolbox (76 participants)

On January 2016, EUPATI launched the EUPATI Internet Toolbox on Medicines R&D. This tool made available content on almost all aspects covered by the EUPATI course in 7 languages. It was a great success with more than 100.000 users in one year.

In 2017, EUPATI will continue as the "EUPATI Programme", under the aegis of EPF. The key assets of EUPATI - the Toolbox, and the Expert Training Course - will be maintained and developed, continuing to educate and empower patients for a more active role as partner in all aspects of medicines research and development.

Website:https://www.eupati.eu/

IMI – COMBACTE (2013-2022)

COMBACTE (Combatting Bacterial Resistance in Europe) was the first project to be launched under ND4BB in January 2013 with a duration of 7 years. 6 further Combacte projects have meanwhile been authorised with a joint budget of € 630 Mio.

The COMBACTE programme aims at creating new treatments for multi-resistant infections. In close collaboration between pharma companies and academic institutions, a new pan-European network-infrastructure for anti-infective treatment development is supposed to be established. An important element of this development infrastructure is the building of three pillars of the network: CLIN-Net, LAB-Net and STAT-Net. CLIN-Net aims to establish a highly competent and efficient Europe-wide clinical investigator network to perform antibacterial clinical trials with reliable recruitment and efficient creation of top quality data. Through COMBACTE, hospitals across Europe will be prepared for the clinical studies that are planned under the ND4BB programme. Member sites will be audited and certified for the conduct of clinical trials and will receive training and coaching to optimize their procedures and performance, to ensure their compliance with the required Good Clinical Practice (GCP) standards. Since the programme's start in 2013, 391 hospitals from 37 European countries have expressed an interest to be part of this unique and still growing community. CLIN-Net is currently involved in Phase II and Phase III clinical trials.

The COMBACTE-MAGNET (Combatting Bacterial Resistance in Europe - Molecules Against Gram Negative Infections) project was started in January 2015 and its duration will be 7 years with a total budget of €167 million. COMBACTE-MAGNET brings together 40 partners from the pharmaceutical industry and academia, 17 of which are also partners in COMBACTE. It is focused on supporting the development of agents of MedImmune and AiCuris to prevent and treat infections caused by antibiotic-resistant Gram-negative bacteria, as well as establishing an epidemiology network, called EPI-Net. The main goal of EPI-Net is to develop a coherent epidemiology strategy and organize pertinent expertise and available data sources in Europe and across ND4BB in support of public health and drug development priorities related to antimicrobials.

EFGCP has been invited to join COMBACTE-MAGNET as a consortium partner involved in the training of the project's investigators. However, it turned out quickly that EFGCP could play a much wider training role in the overall COMBACTE programme. EFGCP developed a two-day applied GCP training programme for clinical investigators working in intensive care units. In addition, EFGCP has been invited to support LAB-Net in developing and delivering a GcLP training programme for their lab staff members in all participating hospitals.

In 2016, EFGCP conducted two GCP trainings for COMBACTE:

- COMBACTE CLIN-Net Investigator's GCP Meeting, *13th April 2016, Budapest, Hungary, 29 participants*
- Combacte NET – EFGCP Course: Applying GCP in the Combacte Studies, *22 & 23 September 2016, Athens, Greece, 55 participants*

Website: www.combacte.com

SCHEDULED UPCOMING EVENTS IN 2017

CONFERENCES & WORKSHOPS ORGANISED OR CO-ORGANISED BY EFGCP

EFGCP Annual Conference 2017 on
Meeting the Ethical Standards under the Clinical Trials Regulation:
The Burning Questions (and Answers) for Researchers, Sponsors and Patients
21 & 22 February 2017, BluePoint Conference Centre, Brussels, Belgium

Joint EFGCP-EFPIA Multi-Stakeholder Workshop on
Communicating Clinical Trial Results to meet Public Needs
- Working towards Implementation of Lay Summaries-
2 May 2017 Brussels, Belgium

EFGCP Multi-Stakeholder Workshop on
Quality and Innovation in Complex Studies
12 June 2017, University College London, United Kingdom

EFGCP Multi-Stakeholder Workshop on
Ethical and Efficient Clinical Trials in Paediatric and Geriatric Patients: What can we Learn?
to be confirmed - July 2017

Joint DIA/EFGCP/EMA Better Medicines for Children Annual Conference
October 2017, London, UK / (organised by DIA)

EFGCP Multi-Stakeholder Workshop on
Ethical Considerations on Clinical Research in Pregnant Women
to be confirmed -Fall 2017, Brussels, Belgium

EFGCP Annual Conference 2018 on
Enabling Protocol Compliance - From Human Factor to Technology -
20 & 21 February 2018, Brussels, Belgium

EFGCP MEETINGS

EFGCP Board Meetings

20 February 2017, Courtyard Hotel by Marriott, Brussels, Belgium
1 June 2017, EFGCP Offices, Brussels, Belgium
12 October 2017, EFGCP Offices, Brussels, Belgium
19 February 2018, Brussels, Belgium

EFGCP Annual General Assembly Meeting

20 February 2018, Brussels, Belgium

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