HIGHLIGHTS FROM THE EUCROF GENERAL ASSEMBLY
1 – 2 DECEMBER 2015, Athens

As usual, the representatives of member organizations met at the end of the year. Great thanks to the HACRO colleagues for the organization and support. The GA started with a summary presented by the Executive Board on the activities carried out in 2015, in order to make everybody aware of what happened in the year 2015.

EUCROF Members. In total the coverage of countries has not changed. Ukraine has a new member. Slovakia attends as a guest (Juraj Gaplovsky).

EUCROF's mission. The Federation's goal is to promote Clinical Research by improving the knowledge, competence and skills of CROs in Europe. This has been done in many ways:

- **EMA stakeholders meetings:**
  - GCP IWG
  - EU Portal and Union database
  - ENPR EMA meetings, well attended by the Paediatric WG
  - Pharmacovigilance (which became a trigger for a new WG)
  - SMEs (small and medium enterprises). Pt and disease registries for post-marketing studies meeting. SMa attended 4 meetings in 2 days – EUCROF has been building up its reputation, we represent the European CRO business. We need to step into the EU Commission in Brussels.
  - isource, iCRO, cloud applications, risk based monitoring presentation delivered by Michele Garot on 30 November 2015. EUCROF presented a constructive approach, which was strongly appreciated.

Some of the working groups activities:

- **Clinical Trial Legislation:** Mainly worked on the Clinical Trials Portal and in particular on rules for publication of clinical trial results. There has been a great achievement: ("*Sponsor may opt to defer the publication of the summary of results and layperson summary in all or in part up to a maximum of 18 months after the due date (usually 12 months after the end of the trial …)*This is very beneficial not only for Phase I trials, but for the whole clinical trial environment in Europe.
- **The Outsourcing Management:** Since October 2013 there has been a collaboration between EUCROF and PCMG (Pharmaceutical Contract Management Group). Both associations provide the other one with three free entries at their conference and they both advertise each other's conferences on their websites. Now the aim of the new co-operative work stream is to finalize KPIs for biometrics and balanced scorecard by September 2016.
- **Medical Devices:** This is a particularly active group with webinars. 2 webinars in 2013 and 2 in 2014.
- **Paediatrics:** One of the most important new initiatives is the creation of the European Paediatric Network. The execution plan would go over 5 to 10 years. The WG will be supporting the design, check the metrics. The goal is to have a global net that should be developed both in Europe and Asia. Other important activities are the collaboration with EFCGP and ENPR EMA.
- **Education & Training:** The ETWG focused on one thing: ensure that the webinars were also for external people, non-EUCROF members. In collaboration with the Communication WG, the web tools for registration and payment for the webinars were set up.

- **Communication:** Important activities – technical support and preparation of webinars. Otherwise: Our mission is to develop training education in CT. Why not evaluate the use of videos? Further work is planned in this field.

Subject matter experts are needed for meetings to represent EUCROF at meetings. Call for candidates! Each application for a subject matter expert should be accompanied by a CV or a resume. Experts may be found among the members of the WGs or among the employees of our companies. We have regular demands for EUCROF to participate in meetings where the expertise is needed.

Our guest: Introduction to the Slovakian Association (Juraj Gaplovsky).

SACROP is the Slovakian Association of CROs and Professionals in the clinical trial industry. The Association was founded in 2012. It is quite young and small and it also integrates freelancers who deal with CTs. Its mission is the integration of entities (CROs, freelancers) that deal with clinical research and development of medicinal products and medical devices; improvement of relationships among CROs, pharmaceutical industry, competent authorities and ethics committees; improvement of quality of work within industry and increasing of overall awareness about clinical trials in patient population.

The GA attendees were also invited to attend the **HACRO Symposium** as well as the **HACRO dinner** at the roof restaurant of the Royal Olympic Hotel.

Plans:

The next GA: DIA Hamburg (6 - 8 April 2016 – We/Fri), 7th April (Thursday) at 17.00 – evening.

The next End-of-the Year GA venue Munich 29, 30 Nov 2016 .

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