EUCROF
European CRO Federation

Medical Device Working Group

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Status June 2014

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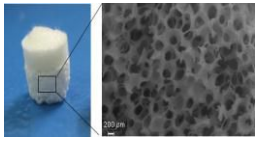
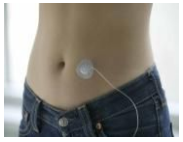
The European CRO Federation,
one voice towards clinical research






Our Goal

The **EUCROF Medical Device Working Group** provides a forum for discussion of various aspects of clinical research associated with Medical Devices. It is our objective to share our CRO-based experience with stakeholders involved in the area. On the long term we want to become a recognised partner and aim to be involved in the development of regulative framework.
As a group, we contribute extensive experience from our daily work and assist sponsors by guiding them through the myriad of regulations in Europe, in EU member states and worldwide. We consider appropriate and good harmonization of regulations to be important to the development of safe and innovative medical devices, as needed for patients and as mandated for qualified Health Care Systems.

Patient access to medical devices frequently starts during clinical investigations. Also, following market approval, ongoing further investigations on safety and long term aspects gain more and more importance to ensure worldwide safe positioning of devices on the market . The work of our group seeks to target harmonized understanding of current regulatory requirements for clinical investigations with Medical Devices, to contribute to compliant performance of clinical investigations, to support the protection of patients, and to exchange experience with interested groups.

Activities and Members

The Working Group started in 2012. Nevertheless, in 2013 the focus was set on deciding, developing and delivering training materials to better understand the regulatory framework to conduct investigations with Medical Devices in EU. This was managed during one face-to-face meeting in March 2013 and monthly TCs.

The Working Group has now (status June 2014) 12 active team members from 10 CROs that regularly attended TCs and were involved in the preparation of deliverables. They are located in 6 countries: Belgium, France, Germany, Greece, Spain and Turkey. Chair of the Group is Susanne Gerbl-Rieger from CROMSOURCE and she is supported by Co-Chair Judith Köhnen from Theorem Clinical Research.

Member Associations

Belgium
Belgian Association of CROs (BeCRO)

Germany
Bundesverband Medizinischer Auftrags-institute e.V. (BVMA)

Greece
Hellenic Association of CROs (HACRO)

Turkey
Sözlesmeli Arastirma Kuruluslari Dernegi (SAKDER)

Spain
Asociación Española de Compañias de Investigación Clínica (AECIC)

France
L'Association Française des CROs (AFCROs)

Achievements until end 2013

The group provided training material, which is used for EUCROF Webinar initiatives. Actually the pilot Webinar dated 25.09.2013 was supported by a presentation on "Requirements for Clinical Investigations with Medical Devices - Clarity about the actual regulatory framework - basis to understand the future". Additionally further Webinars were hosted on ISO 14155: 2011.

The Working Group contributed to the first EUCROF Conference 07.-09.10.2013 in Brussels. During the two workshop sessions dated 9 October 2013; 08:00 to 10:00 the Medical Device Working Group reported the activities in detail and presented "What Changes with the New Medical Device Regulation? Impact on Clinical Research and Market Approval".

Achievements and Plans for 2014

The group will further develop and provide training material, to be used for EUCROF Webinar initiatives. A focus will be the follow-up of the recast of the MDR and IVDR. Already scheduled or planned actions are:

- Monthly TCs
- FTF Meeting : 16.04.2014
- EUCROF Webinar : 29.04.2014 - SAE and Incidence Reporting
- Q3/Q4 : Further webinars planned depend on publication of MDR and IVDR and on needs e.g. IVD Webinar planned for 06.11.2014