EUCROF
European CRO Federation

Medical Device Working Group

Chair: Mieke Tempels

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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 recognized 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 implementation of the MDR 2017/745 in EU member states and worldwide.** We consider appropriate and good harmonization of regulations to be important for placing and keeping safe and innovative medical devices on the market, 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 are required 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.

Action Plans

- Relationship with Regulatory Authorities
- Planning meetings/webinars
- Preparation of documents/guidances
- IVDR
- Combination products
- Clinical Investigational Plan vs Clinical Evaluation Plan
- Hardware/software
- Mapping the available info in one spot

Published Documents

- Clinical Evaluation vs. Clinical Investigation & Combination products: https://www.eucrof.eu/news-eucrof/publications

- Medical Device Regulation (MDR) Useful Links: https://www.eucrof.eu/news-eucrof/latest-news

Webinars

- Medical Device Software: Shaping the Future of Clinical Research and Healthcare
- Medical Device Regulation (MDR): Challenges, Opportunities & Best Practices in Clinical Trials

Members

1	Mieke	Tempels	Archer Research	Belgium	Chair
2	Antoinette	van Dijk	D.O. Research	Switzerland	Co-chair
3	Karen	Gabriels	Archer Research	Belgium	Member
4	Şebnem	Yaşaroğulları	Mene Research	Turkey	Member
5	Natalia	Gordieyvskaya	ULC-Ukrainian Logistic Cluster	Ukraine	Member

Interested in the Medical Device Working Group (WG)?

- If you are interested in becoming a member of the Medical Device WG, please contact:

✓ EUCROF Secretariat : info@eucrof.eu or
✓ Chair of the WG: mieke.tempels@archerresearch.eu or
✓ Co-Chair of the WG: antoinette.vandijk@doresearch.ch

- We are looking forward to hearing from you!