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History and Mission

Emergo by UL's CRO specializes in clinical investigations and PMCF activities with medical devices. Our experienced team offers services related to the design, conduct, quality control, and evaluation of these clinical activities regarding active and non-active medical devices. We contribute to our clients' success by delivering high-quality clinical data.

Highlights

As of May 26, 2021, the European Medical Device Regulation (MDR) is in effect. This regulation reinforces the need for the availability of clinical evidence, which can be collected via clinical investigations prior to CE-marking and via post market clinical follow up (PMCF) activities once the device is marketed. The extent of these pre-CE and PMCF studies required depends on the risk class and the complexity of the medical device. PMCF activities, however, need to be planned and conducted for all medical devices marketed.

Our experience in the medical device clinical research business makes us a strong and reliable partner for our customers.

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BVMA member since 2005
Audits passed in 2005, 2006, 2009, 2012, 2016 and 2019

EMERGO by UL

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Services

Study and PMCF study design
The design of any clinical activity defines costs, duration and the likeliness of success. Especially proper sample size determination (number of patients included) as well as known and potential risks, need to be carefully addressed. Our clinical research experts will support you in planning your clinical activity most efficiently (costs and time).

For clinical investigations with medical devices, we offer reviews of documents, systems, and procedures. The intent of these reviews is to ensure data capture, analysis, and that reporting is in accordance with the study plan and in compliance with ISO 14155, GCP, and regulatory requirements, as well as the Sponsor's Standard Operating Procedures (SOPs).

Study submission requirements
Our clinical experts provide guidance on clinical study submission and approval or notification requirements for many European countries. This includes studies with combination products as well as PMCF studies.

Additional services offered by Emergo by UL to further help device manufacturer (sponsors) to plan, set up, conduct and evaluate clinical studies with high quality and cost efficient are:

- **Project Management and Quality** to ensure adherence to timelines and targeted budget as well as compliance with legal and regulatory requirements.
- **Monitoring** (on-site and remote) to verify that data is collected according to the study protocol and ISO 14155 and that adverse events and incidents are adequately documented and recorded.
- **Data Management** which includes CRF design and database set up supervision as well as data processing in accordance with the data management plan (DMP).
- **Biostatistics** to provide valuable input to the design of your clinical study. This includes thorough assessment of the scientific requirements for proper sample size determination and evaluation methods to be used.