



CLINICAL AFFAIRS

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### Regarding the clinical application of your medical device

As a manufacturer, you need to guarantee the safety and performance of your product over its entire life cycle. While safety is primarily addressed within risk management, the performance (i.e. the clinical benefits) is presented in the clinical evaluation and is continuously evaluated by ongoing market observations. We'll be pleased to support you with this.

### Your benefits

- The right strategy and appropriate processes will ensure you have a safe and effective medical device.
- We act as a competent partner to test laboratories and clinical investigators.
- At the end of the project, you'll know everything you need to know to keep your clinical evaluation documentation up-to-date yourself.

## CLINICAL AFFAIRS IN A NEW LIGHT: WHAT CHANGES ACCOMPANY THE MDR?

The MDR (Medical Devices Regulation) turns the requirements for clinical evaluations on their head. While it would have been enough to base the evaluation on comparability with another product (under MDD) the MDR puts the emphasis firmly on collecting your own clinical data: Only those able to view their competitor's product files may base their clinical evaluation on the principle of equivalence. Whoever has their own predecessor and comparison products can continue to use these if sufficient clinical data is available to do so.

We'll develop an individual strategy for you regarding the generation of clinical data, support you in the establishment of PMCF processes and plans and accompany you in the implementation of PMCF activities.

### OUR SERVICES

#### Clinical evaluation based on literature

- Clinical evaluations based on literature according to MEDDEV 2.7/1,
- Vigilance according to MEDDEV 2.12-1 and strategy for clinical evaluations over the entire product life cycle,
- Advice, training and workshops on the MEDDEV 2.7/1 guideline and its implementation,
- Contact with clinics ("medical experts").

#### Clinical trials / Clinical monitoring

- Clinical trials according to Medical Products Act (MPG), ISO 14155 and Good Clinical Practice (GCP),
- Provision of clinical monitors,
- Advice, training and workshops in respect to official regulations,
- Contact with clinics and test laboratories.

#### PMS/ PMCF

- Support and advice regarding post-market surveillance (PMS),
- Post-market clinical follow-up (PMCF) studies: regulated in the Medical Products Act and according to MEDDEV 2.12/2, are also conducted according to ISO 14155. Metecon will assist you in the planning and implementation of these clinical trials.

***„We won't just simply compile your clinical evaluation.  
We'll enable you to keep your clinical evaluation documentation  
always up to date over the entire product life cycle“***

*Katharina Thievensen, Head of Clinical Affairs  
& Verification*