



## PMCF ACTIVITIES

### MDR: No clinical evaluation without own data

Manufacturers have to assure the safety and performance of their device over the entire product life cycle. Both, safety and performance, which make up the clinical benefit of the device, have to be determined through a continuous market surveillance and reported in an updated clinical evaluation.

With the new MDR, the requirements on clinical evaluations will now be turned upside down: While in the past the clinical evaluation based on literature data and demonstration of equivalence of the device with that to which the data relate was sufficient, far more own clinical data have to be collected.

### How can the need for clinical data be identified?

1. Identification of the clinical functions of the product
2. Assessment which of the clinical functions can be verified by preclinical studies
3. Investigation and appraisal of suitable literature concerning the clinical functions
4. Analysis of the requirements for Post Market Clinical Follow-Up (PMCF) activities.

## PMCF (POST MARKET CLINICAL FOLLOW-UP) WILL BECOME MANDATORY

With the MDR, manufacturers have to plan PMCF activities. In particular, as an integral part of the technical documentation, and as regulated by the Quality Management System (QMS), it will be required to systematically collect data to verify the safety and clinical performance of the device.

The collection of clinical data through PMCF is a continuous process to regularly update the clinical evaluation. The advantage: Concerning organization and implementation, PMCF studies are less demanding than clinical trials in order to obtain CE marking.

## PMCF ACTIVITIES

In case clinical data are needed, the following concepts are often suitable:

- Follow-up of patients recruited for clinical trials before CE marking
- Observational studies (collecting data under routine conditions)
- Retrospective analysis of data collected from users and patients experienced with the product
- Analysis of other post market surveillance activities (for example: service reports, hotline calls, customer complaints etc.).

## CLINICAL AFFAIRS UNDER NEW PREMISES

To be successfully prepared for the future, the necessary expertise in topics of clinical evaluation and verification alone will no longer be sufficient. Established knowledge and experience about the techniques to evaluate the clinical functions of the product in relation to the new requirements will be required. In particular, this know-how is needed to establish what is adequate enough to verify the efficacy of the product. In many cases, in vitro and bench testing can replace cumbersome clinical trials.

Metecon draws up individual and suitably strategies aimed at collecting clinical data, assists with the preparation of PMCF processes and plans, and supports you with the successful realization of the required PMCF activities.

**We are looking forward to meeting you!**