

Creation and use of an electronic, clinics and patients comprehensive, monitoring and tracking system (PMCF system) for class III medical devices using the example of arterial stents or of hip implants

**Statistische Analysen und
Monitoring GmbH
Tittardshang 5
52072 Aachen**



The PMCF system is designed to produce and prepare data for Class III medical devices involving clinicians, manufacturers and patients in pre-, intra- and post- surgical clinical routine and to monitor the clinical and non-clinical follow up of the implant carrier in accordance with the requirements for PMCF (Post Market Clinical Follow Up) data of the new MDR (Medical Device Regulation) of the EU.

The inclusion of patients in the monitoring of these medical devices (mostly implants) is a world first, and for the first time would allow reliable data from health assessments and risk estimates, taking into account previously unrecognized positive assessments of tolerability.

Compliance of the system

The underlying RDE system meets all EU requirements for such systems.

In addition, it meets the criteria of

FDA 21 CFR Part 11 - ELECTRONIC RECORDS;
ELECTRONIC SIGNATURES

as well as the requirements for

eCRF, Electronic Signatures and Electronic Source Data der
PMDA authorities (Japan)

and the TGA authorities (Australia).

Details and roles of partners sought:

- a) We are looking for manufacturer of Class III devices (e.g. hip implants, stents etc.)
- b) We are looking for implant clinics or implant centers

Scientific and technical expertise:

Successfully carried out 8 multicenter 2 – 3 years lasting clinical projects funded by the German Federal ministry of Technology and Research, 1 multicenter project funded by the science ministry of NRW, Germany.

Development of a modular, self explanatory remote data entry system for clinical trials that contains modules for investigators, monitors, data managers, vigilance experts and patients and complies to all requirements for such systems of the EMA authorities, of the FDA and of the Japanese and Australian authorities.