ISS
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

POST MARKET CLINICAL FOLLOW-UP STUDIES (PMCF)

Due to substantially more stringent requirements regarding acquisition of data about safety and performance of medical devices following placement on the market, many manufacturers must plan and implement PMCF studies.
ISS AG as an audited CRO (Clinical Research Organization) has designed and implemented successful PMCF studies of various designs and for all risk class of Medtech products. Together with you we develop a PMCF plan that suits your needs and capacities. We work out an appropriate study design and supervise its implementation from study initiation to filing of the PMCF report.

PMCF studies are a systematic approach of acquisition of relevant clinical data for supporting your product on the market. As such they are clinical trials according to current legislation and subject to approval. A PMCF study must be implemented in line with Good Clinical Practice, for medical devices as per ISO 14155.
ISS AG knows the needs of Medtech manufacturers and the ways Notified Bodies and Compentent Authorities interprete and enforce the challenging and fast-evolving regulatory requirements. Whether prospective or retrospective data acquisition, Health Care Provider or patient survey, real-world evidence analysis or full-blown clinical postmarket study, we can develop a lean PMCF solution in compliance with regulatory requirements that suits your company's needs and capacities.

Your responsibility

As a manufacturer you are responsible for the proper implementation of PMCF studies according to regulatory requirements and pertinent guidances, but you can outsource certain tasks to a qualified service company (CRO).

Our services

We process the entire design and implementation of the PMCF plan for you or assume selected packages:

- Set-up of a PMCF plan as per requirements of guidance MDCG 2020-7
- Compilation of the submission dossier for ethics committee approval
- Initiation, supervision and monitoring of the PMCF study as per ISO 14155
- Data management and statistical analysis with validated tools
- PMCF evaluation report as per requirements of guidance MDCG 2020-8
- Medical Writing of regulatory and scientific documents
- Project planning, budgeting, and management.

Your benefits

ISS AG CRO is a Swiss-based company focused on the MedTech industry. A highly skilled interdisciplinary team and a long standing experience with clinical studies of medical devices provide the essential know-how and the networks that qualify us to offer lean solutions for you to meet PMCF requirements in line with applicable regulations and guidances, while addressing marketing needs.

Our team

The ISS team comprises around 40 employees, by the majority with a background in engineering, science, humanities, or medicine. As Switzerland's largest service company specialised in medical devices, ISS covers Regulatory Affairs, Clinical Services, Quality Management and Engineering, as well as Software Development.

ISS CRO processes are audited by the BVMA

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