If a PMCF study is required, observational trials are especially effective instruments for Post-Market Surveillance. The product is analyzed during routine use in selected hospitals, and these studies follow a non-interventional protocol which does not allow interference with patient care. Possible study designs include also registries, and the results are analyzed at specific intervals.

As a Contract Research Organization (CRO) we have been certified to carry out contract research in the field of medical technologies according to ISO 9001.

Your benefit

novineon CRO will either use your own clinical data or current scientific literature to create a comprehensive Post-Market Surveillance report. Drawing from a sound database, this document can be updated continually and describes the risks and clinical benefits of your medical device in accordance with official guidelines and regulations.

The structure of the Post-Market Surveillance report allows for quick integration of new data into the clinical evaluation, which is also provided by novineon CRO. This guarantees that the clinical evaluation is up to date, as required by MEDDEV 2.7.1.

We focus on providing customized, comprehensive solutions for our clients, offering fast and professional support regarding the complex subjects of Post-Market Surveillance and clinical evaluation. Existing cooperations between your company and clinicians can be integrated into the collaboration with novineon CRO if so required.

As our client, you are involved in the process from the beginning and receive continuous updates about all relevant aspects.

Who we are

novineon CRO & Consulting Ltd is a consulting and research company in the field of health care technology. As a professional service provider situated at the interface between scientific research and business and industry, we are operating worldwide. Our CRO (Contract Research Organization) division supports manufacturers of medical devices in all aspects of preclinical and clinical research as well as regarding product authorization.

We work with an international network of leading medical facilities and institutions, and our clients include international healthcare companies as well as medium-sized enterprises and start-up companies.

For further information on Post-Market Surveillance, PMCF and clinical evaluations, please visit: www.clinicalevaluation.com
Post-market monitoring of medical devices

Guidelines 93/42/EEC and 90/385/EEC require manufacturers of medical devices to implement post-market device monitoring programs (Post-Market Surveillance, PMS) into their quality management system, which examine the clinical efficacy and safety of their products. These Post-Market Surveillance measures are important to detect rare incidents and complications, which may only become visible under widespread and long-term use of an approved medical device.

Post-Market Surveillance

In many cases, a structured monitoring process of clinical data in scientific literature according to pre-defined criteria is an appropriate method of Post-Market Surveillance. Published literature and, whenever possible, conference papers and proceedings are reviewed as to their relevance to the respective medical device. This literature monitoring should be performed at defined time intervals. The resulting Post-Market Surveillance data can also be used for keeping the clinical evaluation up-to-date as required by MEDDEV 2.7.1.

Post-Market Clinical Follow-up

The 2012 version of MEDDEV 2.12/2 defines Post-Market Clinical Follow-up (PMCF) studies as an essential part of Post-Market Surveillance. As of 2012, medical device manufacturers are strongly encouraged to consider the requirement of Post-Market Clinical Follow-up (PMCF) studies. PMCF studies are mandatory if the clinical evaluation for the initial conformity assessment of the medical device is entirely based on equivalent devices. Furthermore, PMCF studies are required, for example, for innovative products, for high-risk devices, and if the safety and efficacy of the medical device have so far only been shown for a selected patient population.

PMCF studies are to be carried out according to documented, proactive and well-organized methods and procedures, which are determined by an individual PMCF plan. These PMCF studies may include:

- continued follow-up of patients from clinical investigations before market approval
- new clinical investigations
- analysis of data from observational studies (e.g., registry)
- analysis of relevant retrospective data of treated patients

MEDDEV 2.12/2 explicitly demands implementation of the PMCF by qualified experts.

Notified bodies have to review the manufacturer’s Post-Market Surveillance plans and activities, including PMCF, as part of regular audits.

Implementation

It is essential for medical device manufacturers to develop Post-Market Surveillance- and PMCF-plans and activities that are appropriate and suitable for the product as well as in accordance with current regulations. The key for this is the development of a customized and manageable company-specific strategy for Post-Market Surveillance and PMCF.

Our services

Based on the requirements of current regulations, we develop and implement methods for an efficient Post-Market Surveillance for you, which is in accordance with the Directive:

- Consultation on Post-Market Surveillance and design of a suitable Post-Market Surveillance program.
- Design and periodic updates of a Post-Market Surveillance report for your medical devices as part of an ongoing Post-Market Surveillance program.
- Development of an active Post-Market Surveillance program as appropriate alternative to clinical PMCF studies.
- Revision of your clinical evaluation based on Post-Market Surveillance data and in accordance with MEDDEV 2.7.1.
- Revision of instructions for use, patient information sheets, etc. based on Post-Market Surveillance data.
- If required by MEDDEV 2.12/2, we also provide consultation on the design and management of PMCF studies.

Our Approach

Based on your technical documentation and available scientific literature, we objectively assess your situation and consult with you regarding the suitable implementation of the requirements given by guideline MEDDEV 2.12/2.

The Post-Market Surveillance report created for your medical device explains and documents the chosen PMS approach in accordance with MEDDEV 2.12/2. Within the scope of this report, we prepare a systematic review and, if possible, a meta-analysis based on the principles of evidence-based medicine according to the standards laid out in the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and on the principles advocated by the international Cochrane Collaboration.

A meta-analysis is a systematic, quantitative method for combining relevant research results from different studies using statistical methods. In accordance with EU guideline 93/42/EEC, we use available scientific literature about your product or equivalent products as the data base for our analysis. In case you have clinical data for your medical device available from your own studies or from collaborations with physicians, we also analyze these datasets and integrate the results into your Post-Market Surveillance report.

As part of an active Post-Market Surveillance program, we provide user questionnaires and analytical methods customized specifically for your medical device. The standardized structure of these questionnaires guarantees fast and targeted data processing and evaluation, ensuring high-quality active Post-Market Surveillance.

Our services

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