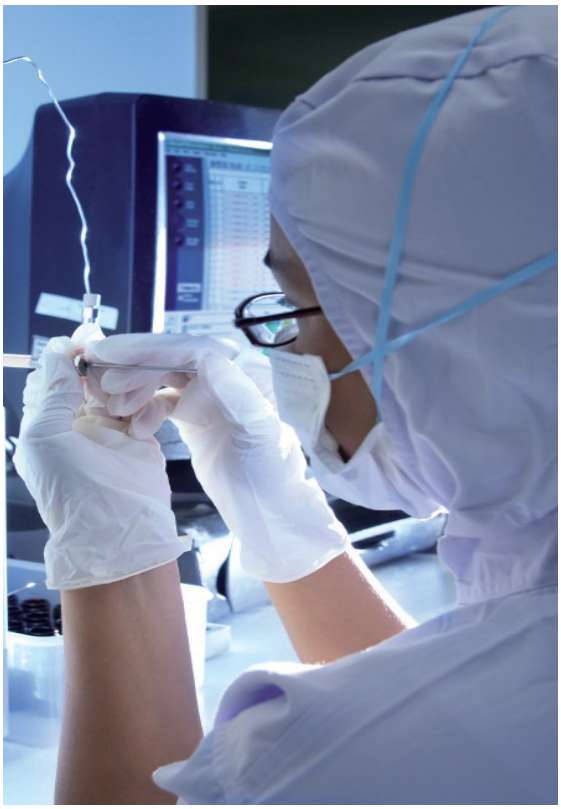
GEMAR

Medical Health Services

Reaching the market in time

A global approach for medical devices opinion



Clinical Investigation

Your Notified Body is requiring you to have more and compliant Clinical Data. Clinical data should be state-of-the-art and in conformity with the requirements of MEDDEV 2.7.1 and ISO 14155.

For devices already on the market, there are increasing demands being made on the Post Market Clinical Follow up. In order to be in compliance, your Technical Documentation needs to checked and further updated. It may also mean that to maintain compliance, a limited field study is necessary. For new devices, there are increasing requirements in the form of relying on your own clinical data, and not only on clinical data gathered from literature. Depending on the technology and classification, the required data can range from patient evaluations to controlled and randomized clinical trials.
You need a reliable partner that provides you with practical hands-on experience. This starts with a thorough understanding of the requirements, translated to your devices. After indicating the gaps, if any, you need a practical approach to become, or remain, compliant.

We, at Gemar, have successfully showed that we can deliver this practical approach. Our Clinical Support Service is integrated into our daily consultancy work. That means you continue having one contact person, who will manage your request for clinical support. Gemar's clinical team, with experienced clinical staff members, including an MD, will assist in clinical activities.

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We bring you to market faster!

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Our clinical support covers a wide range of services: definition of the clinical strategy; writing a clinical evaluation report in line with MEDDEV 2.7.1; communication and discussion with your Notified Body, or when applicable with (drug) authorities; support in selection and assessment of sites for optimal study conduct; statistical data analysis; and writing clinical study reports.

Examples of more detailed clinical support services are listed below:

- Clinical Strategy
- Clinical Evaluation (MEDDEV 2.7.1)
- Clinical Investigation Study Design and Protocol Development
- Site Feasibility & Selection
- Site Training and Initiation
- Recruitment Assessment & Solutions
- Medical Device Clinical Investigation Management and Monitoring the conduct of the study (Monocenter/ Multicenter)
- Validation and verification of data
- Safety reporting & (S)AE handling
- Interim/Final Report
- Post Market Clinical Follow Up
- Training on Clinical aspects
- Clinical Consulting
- European Authorized Representative Services (EAR)

Following hundreds of clinical evaluations we have prepared for our customers, we have the experience to successfully guide you through the Clinical labyrinth. With our in-depth knowledge of the building of technical dossiers and the submission of the files to the Notified Bodies, we have been able to establish a high success rate in securing CE-marks for our customers.

Gemar provides complete **"One Stop Shopping"** support to efficiently secure your Market Approval (MA).

We also provide **training** in all aspects of the development and regulatory process.

For more information and to answer specific questions, please contact:

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