The Smerud Medical Research Group (SMERUD) is a clinical Contract Research Organisation operating in the Northern European area with head office in Norway and subsidiary offices in Denmark, Finland, Sweden, Poland, Russia and the United Kingdom. Our activities are primarily focused on clinical project management and monitoring of phase II-III studies, regulatory affairs, data management, medical writing and general drug development consulting. The company employs about 80 persons, of whom 70 are clinical research, regulatory or biostatistical professionals. We have been operating since 1993 with involvement in more than 600 clinical trials and more than 300 regulatory projects, in addition to approximately 100 projects related to data management, biostatistics and medical writing. Our international management team based in Oslo (Norway) consists of senior professionals with many years of experience from the international pharmaceutical industry, academia as well as the consultancy business. The local country operational country units, each counting typically 10-35 CRAs, are headed by country managers, all with several years' practical experience from clinical research.

SMERUD MEDICAL RESEARCH

- Experts in proof-of-concept clinical trials

Specialised in clinical development consulting to biotech companies

SMERUD is ideally sized and experienced to be a preferred partner for biotech companies in terms of managing early clinical trials in a cost-effective setting. Our core competence is expert consulting as well as operational services from clinical proof-of-concept trials (phase IIa) up to and including pivotal phase III trials, and subsequently the regulatory submission. Being a relatively small company and operating in transparent markets, SMERUD has maintained a client-focused and flexible attitude. This is particularly important in managing biotech clients as we frequently experience that such clients wish to keep a very close control on study progress. We are used to this, and acknowledge the close collaboration often needed in the early trials. We value the partnership philosophy, but are nevertheless compliant with agreed milestones. Our project managers have been carefully selected and trained to understand the quality and result-oriented environment in today's contracting market. Dedication to the projects, and a clear vision of professional pride, make us important providers of clinical development services in Northern Europe. SMERUD has been selected as development partner for a number of biotech companies, and we are proud to learn that we are frequently asked to provide further and expanded services to those clients.

Despite being a relatively small CRO, we have developed a full-service organisation offering all operational services needed to develop a drug from first-in-patients until compiling the application for marketing authorisation. Of particular importance is the statistical consulting, as proper choice of study design and choice of statistical methods including modeling, is vital to a cost-efficient critical path. Our close collaboration with academia and continued investment in statistical research projects, position us well in terms of offering highest quality advice. Our knowledge base also includes innovative study designs, aimed at exploiting often relatively scarce funding for early phase trials, especially through start-up biotech companies. Examples include i.a. Bayesian approaches, adaptive randomisation as well as group sequential interim analyses.

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Services:

- Clinical Development Consulting
- Clinical Project Management
- Monitoring
- Data Management and Statistics
- Regulatory Affairs
- Quality Assurance
- Training Courses