ÅKRN
Scientific Consulting

Clinical Research Experts for In-Vitro Diagnostic & MedTech.

Why ÅKRN as Medical Device CRO?

We are flexible, agile, and with solid medical device expertise. We offer optimized regulatory and clinical services tailored to our clients and MedTech partners.

Our qualified clinical and medical professionals have the expertise to design and manage studies that demonstrate the safety and performance/efficiency of medical devices and in-vitro diagnostics. We help our clients before and after entering the European market by guaranteeing a timely set-up of clinical trial activities and establishing efficient research solutions.

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A Perfect Partner for MedTech Companies and Startups

We can meet short turnaround times, which is extremely important for the medical device starts-ups during the development phase, where clinical milestones demonstrate the value of the new technology and guarantee the next round of financing.

As a medical device CRO, we develop clinical studies for all medical devices (Class I, Class II, and Class III) according to the new EU MDR 2017/745. We also design and setup performance studies for in-vitro diagnostic devices (Class A, Class B, Class C, and Class D) under the new EU IVDR 2017/746.

Our team specializes in medical devices in the cardiovascular therapeutic space, and we aim to be the most experienced and knowledgeable European CRO in this field today.

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Medical Device
In-Vitro Diagnostic Expertise + Optimal Design

Our success comes from providing our valued clients with a combination of medical and technical expertise within a tightly controlled budget. Our regulatory work is exclusively focusing on European medical device approvals, and we have developed highly cost-effective and efficient processes to achieve excellent results.

We provide unmatched expertise, from initial feasibility trials to market approved products and clinically proven results. Because of this, our clients and partners view us as a trusted and valued adviser in the clinical trial set up and long term study management.

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Who We Are

Grounded in medicine and science, we help sponsors move from medical discovery into clinical development, commercialization, and post-market follow up.

We provide a high level of expertise, and excellent clinical and regulatory services, in a cost-conscious and diligent manner. Our experience covers a wide range of medical device therapeutic areas, including neuroscience and cardiovascular devices.

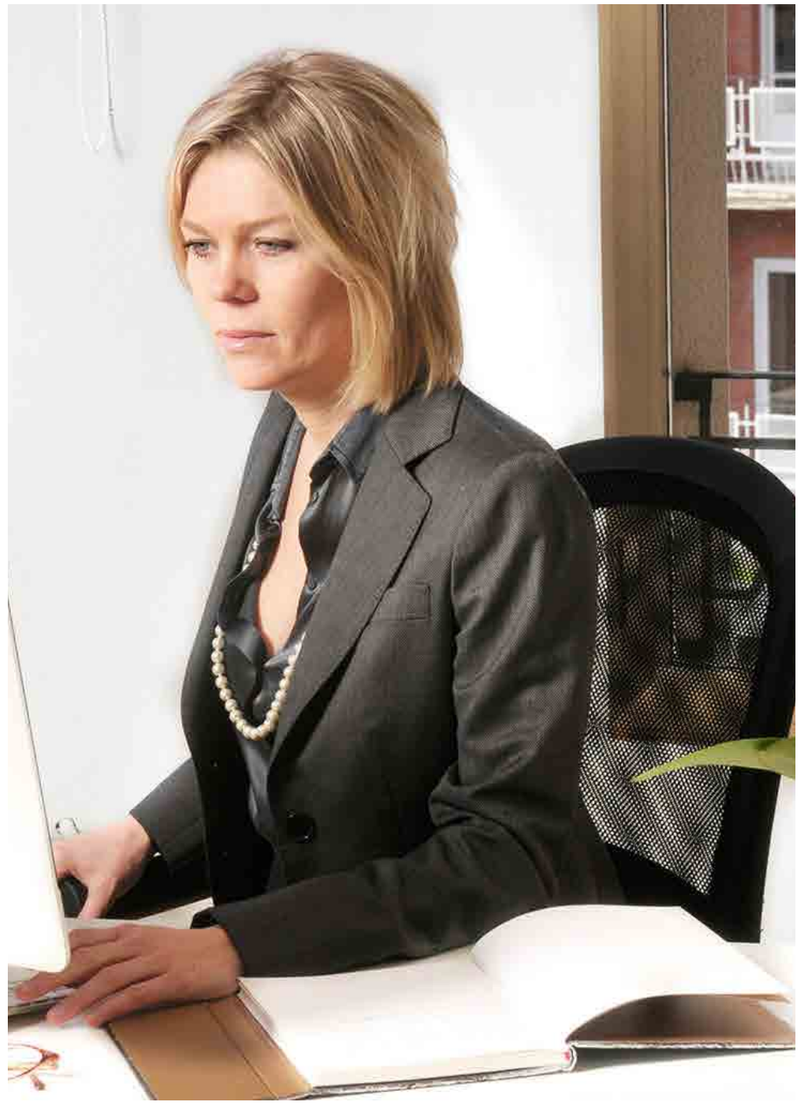
We are a multidisciplinary team collectively fluent in eight European languages. Our research specialists and clinical professionals have higher scientific degrees, including Ph.D., Pharm.D., and Masters in Clinical Research.

Our team specializes in medical devices and in-vitro diagnostics. We offer a single point of contact, but with the benefit of strong senior management support.

Our success builds upon providing our clients with a combination of medical and technical expertise within tightly-controlled clinical studies and budgets. Because of this, our clients and partners view us as a trusted and valued adviser in clinical trials and development.

"We want to work in partnership with medical device manufacturers creating breakthrough products to provide patients safe and effective treatment solutions."

– Maria Nyåkern, Ph.D.,



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The team

Clinical specialists, medical professionals, and problem solvers.

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05

Code of Conduct

Statement of personal responsibility.

As Clinical and Regulatory Experts, we have the professional and ethical responsibility to maintain the highest standards of conduct when we exercise our professional duties. We take pride in upholding and clarifying the authorities' laws, regulations, and guidelines under which we operate.

We know that we play a pivotal role in ensuring compliance with applicable laws and regulations in developing and commercializing healthcare products.

We honor our core values in this increasingly complex global clinical and regulatory environment. As individual professionals, we are making a positive contribution to public health. We also aspire to embody our code of ethics in our words, actions, and deeds.

- Regulatory Compliance
- Clinical Competency
- Credibility
- Objectivity
- Integrity
- Accountability
- Reason and Honesty
- Dignity and Respect

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06
Areas of Expertise

ÅKRN works with Medical Device and IVD companies around the world in the following therapeutic areas.

- **General**
  - Sepsis Management
  - Minimal Invasive Surgery
  - In-Vitro Diagnostics (IVD)
- **Neurovascular**
  - Neuromodulation
  - Spinal Cord Injuries
  - Neurovascular Mechanical Thrombectomy
- **Cardiovascular**
  - Structural Heart Repair
  - Atrial Fibrillation
  - Hypertension
  - Endovascular Aortic Repair
  - Precutaneous Coronary Interventions (PCI)
  - Transcatheter Aortic Valve Repair (TAVR)
- **Software**
  - AI/Machine Learning SaMD
- **Odontology**
  - Implant and Digital Dentistry
- **Endocrinology**
  - Endocrinology and Diabetes
- **Ophthalmology**

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Clinical Services

Clinical Trial and Consulting Services

We have the expertise to set up and manage clinical trials designed to demonstrate clinical safety and performance of a medical device for CE Marking, as well as obtaining post-market surveillance clinical data on commercialized devices.

We specialize in providing CRO solutions that balance quality, timelines, and budget using scientifically rigorous methods.

Clinical Site Activation

- Clinical strategy and planning
- Study Design & Optimization
- Ethics Committee and Competent Authority
- Submissions
- Clinical Investigation Plan (CIP) Development
- Clinical Site Selection
- Clinical Site Management

Clinical Monitoring

- Qualification Visits
- Site Initiation Visits
- Monitoring Visits
- Source Document Verification
- Close-Out Visits
- Trial Document Handling
- Reporting of Safety Information

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Regulatory Services

ÅKRN partners to support MedTech companies in this process through the following CE Mark Regulatory Strategy Services:

- CE Mark Strategic Planning
- Technical File | Design Dossier
- EU MDD to MDR Transition
- EU IVDD to IVDR Transition
- EU MDR Product Approval Requirements
- EU MDR GSPR Overview
- Product classification and registration of devices
- Clinical Evaluation Reports (CER)
- Notified Body and EU Competent Authorities Contact
- Unique Device Identification (UDI)
- Registration of economic operators

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Medical Writing

Medical Writing and Clinical Reporting

Our extensive experience and therapeutic knowledge are valuable when preparing plans and reports essential for an optimal regulatory strategy.

- Clinical Investigational Plan (CIP) according to ISO14155:2019 and MDR 2017/745
- Clinical Study Report (CSR)
- Clinical Literature Research and Reports according to MEDDEV 2.7/1 Rev 4
- Clinical Evaluation Report (CER) according to MEDDEV 2.7/1 Rev 4
- Summary of Safety and Clinical Performance (SSCP) according to MDR 2017/745
- Post Market Surveillance (PMS) Plan
- Post Market Clinical Follow Up (PMCF) Protocol

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We are pleased to meet you for a first free consultation, where we will advise you accordingly.

Calle Cristo de los Remedios
ES-28703 Madrid

info@akrnconsulting.com
www.akrnconsulting.com