



aCROnordic



Cutting Edge in drug and medical device development



"aCRONordic has delivered a reliable and flexible service to us. They take ownership of the projects they are engaged in, go out of their way to meet customer needs, and deliver outstanding customer service"

Lars Smedegaard Andersen, CEO, Astion

aCRONordic - your partner in development

Flexible solutions

aCRONordic is a Contract Research Organisation (CRO) providing flexible quality solutions in drug and medical device development. We define and deliver unique CRO concepts, covering services all the way from product candidate selection, through evaluation of efficacy and safety studies, registration and product launch.

Find a fast, simple and efficient way to the market

We offer a full range of drug and medical device development services to investors and entrepreneurial companies. Our team can explore product ideas and find the shortest, simplest, and most efficient way to the market.

Furthermore for the pharmaceutical, biotech, and medical device industry, we work as a strategic partner in clinical testing of pharmaceuticals and medical devices, contributing to fulfilment of their goals and future demands for clinical documentation.

Experience and innovation

We have more than 30 years of experience with drug development and clinical trial management. The combination of experience and innovative solutions drive us in delivering outstanding service. We create value, reassurance, and confidence with our customers by having motivated and highly professional employees driving and controlling projects competently and by preparing, planning and conducting logistics carefully.

Professionalism and broad expertise

Everything we do is based on professionalism, control, and close cooperation between multiple experts. We can provide regulatory advice and assistance along with operational quality assurance. At the same time we have the team of professionals that can plan, conduct and complete large scale clinical trials quickly and cost-effectively. We set up an individualised team for every case. Our flat organisation is your guarantee as our customer for a lean process and efficient communication lines.





Development CRO Services

Quality is the keyword and we always adapt to the needs of our customers, reflecting that we define and develop unique CRO concepts. aCRONordic is recognized by our complete range of services in the field of drug and medical device development.

Development Consulting

Drug development is costly and complex. Time to market is the key to success as patent protection time is limited. We strive to find the fastest and most efficient development process for our customers. Our services include:

- Evaluation of new concepts and product opportunities
- Guidance in drug candidate selection
- Establishment of integrated product development plans
- Identification of and contract negotiations with Contract Manufacture organisations (CMO), and other non-clinical CRO's
- Development management support
- Project planning and management

Clinical Research

aCRONordic will provide you with highly qualified professionals within the clinical research field.

Our clinical research function offers expert assistance in any of following disciplines within clinical research:

- Scientific consulting
- Medical writing
- Pharmacovigilance
- Biostatistics
- Clinical data management

Clinical Operations

We have wide experience in organising, coordinating, and executing national and multinational phase I-IV clinical studies in accordance with the ICH, GCP Guidelines and FDA/EMA regulations. Our services enclose:

- CRA-Academy (internal and external training and coaching)
- In-sourcing
- Clinical trial monitoring
- Patient recruitment (feasibility and investigator identification)
- Data entry
- Electronic data capture

Project Management

At aCRONordic we are dedicated to drive and control projects successfully. Our services comprise:

- Management of product development programmes
- Management of clinical programmes
- Management of clinical studies
- In-sourcing of project managers/study managers - and trainees

Regulatory Affairs

Striving for the success of our customers, we provide services within all aspects of regulatory affairs in the support of obtaining marketing authorisations in Europe and US. We ensure a regulatory platform for development, approval, marketing, and maintenance of our customer's products. We offer:

- Consulting on product development
- Maintenance of marketed products

Technical Services

aCRONordic uses updated technology and GCP-regulated IT systems in compliance with CFR 21 part 11. Our technical services are performed using Oracle Clinical and SAS as our principal tools. aCRONordic is a CDISC member and we are constantly following CDISC requirements. Our final trial data are delivered as CDISC compliant SDTM/ADAM dataset. Technical service offers:

- Technical data management
- Statistical programming
- GCP hosting

Quality Assurance

aCRONordic's corporate QA function is designed and applied to assure compliance with the standards of ICH/FCP, FDA, EMA, and OECD. Our QA unit performs:

- Internal QA
- QA/GCP audit
- Support in the selection of contract manufacturers



"aCROnordic is a unique partner in clinical development. We can always trust the timely delivery of high quality performance"

Janne Harder, Nordic Medical Director, Biogen Idec



About aCROnordic

Geographical presence and strategic partners

Our services are fully operational across borders and continents. Headquartered in Denmark, the Nordic area is our home turf, yet we can assist at or conduct any level of drug and medical device development globally. We operate with aCROnordic employees in Denmark, Norway, Sweden, Finland, and Singapore. Furthermore we operate worldwide through an extensive network of local partners. Thus we can deliver services in all parts of the world and in highly specialised business areas.

Our employees

We have a professionally very comprehensive team of experts: physicians, statisticians, nurses, scientists, pharmacists, laboratory technicians, and IT-experts, possessing all the competences needed to handle development CRO-tasks. Moreover our employees share a mutual focus on the process and the overall goal. It is with their skills, drive, and motivation that we ensure timely delivery of quality service. aCROnordic creates added value with reassured customers, by demonstrating that when partnering with us they can confidently leave their product development planning and clinical trial project partly or completely with us. We will see it through.

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