

## Welcome to the first newsletter

In February this year we announced our plans for developing our clinical CRO into a Development CRO. This means that we will be taking responsibility of product development of drugs and medical devices from product candidate selection, through evaluation of efficacy and safety studies, registration, and product launch. We are now well on our way in this process.

With this newsletter we want to update customers and partners on new services as we go along. In addition we will highlight and explore topics of particular interest, e.g. of clinical, regulatory, or operational concern.

In this first issue we can present new services within Medical Affairs, Regulatory Affairs and QA, and Technical Services. We put focus on the concept of aCROnordic Academy which has successfully proven to adapt to unmet needs with our customers. Finally, we now offer services through our own office in Finland.

Without further ado I give you aCROnordic News.

*Søren Strøb*

CEO and founder of aCROnordic



Søren Strøb,  
CEO and Founder

## Mads Engelmann heading Clinical Research at aCROnordic

The Clinical Research team is headed by Mads Engelmann (MD, PhD, and cardiologist) who joined aCROnordic 01 September 2008 as Chief Medical Officer.

Mads Engelmann has thorough clinical and scientific experience within a number of therapeutic areas, particularly cardiology and internal medicine.

In 2005 Mads joined the pharmaceutical industry, where he has worked with product strategy and clinical development, operationally as well as strategically.



Mads Engelmann  
Chief Medical Officer

Mads Engelmann received a degree in Chemical Engineering from the Technical University of Denmark in 1987 and graduated as a medical doctor from the University of Copenhagen in 1993

In 1996 he finished his PhD from the University of Copenhagen, and in 2005 he became board certified as a specialist in cardiology and specialist in internal medicine.

Mads has published a number of scientific articles, acted as author of international scientific textbooks, and has extensive teaching experience.

## New Medical Affairs Services

Medical Affairs comprise a new group of services provided by the Clinical Research team at aCROnordic. Within Medical Affairs we offer our expertise in

- Preparation of product monographs, expert reports, and reimbursement applications
- Medical Marketing consultancy services
- Development and review of promotional material

The team consists of highly qualified professionals within clinical research and medical affairs. In addition to medical affairs experts we offer assistance in Scientific Consulting, Medical Writing, Pharmacovigilance, Biostatistics, and Clinical Data Management.

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## aCRONordic Academy

### In-sourcing of study managers and CRAs in strong growth

The demand for flexible staffing solutions is growing. We have specialised in meeting this demand specifically by providing in-sourcing of study managers and clinical research associates. We hire in trainees who are updated and educated to the specific assignment by experts at aCRONordic. The in-sourced study manager or CRA is in close contact with and have the back up from experts at aCRONordic on an ongoing basis. This reduces requirements for introduction and training on location by the host company. The flexibility of aCRONordic Academy for study management or CRAs solves an immediate demand for resources without any delay caused by hiring, introduction, and training.



Palle Dahl  
Director of Project  
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## Regulatory Affairs and QA

aCRONordic is now offering services within Regulatory Affairs and Quality Assurance. Both units are competently headed by Jeannette Kræmer (MSc Pharm) who joined aCRONordic in August 2008. Jeannette Kræmer has twenty years of experience working with regulatory affairs, quality assurance, and product development. Her extensive expert knowledge in these areas will in the future be supporting aCRONordic customers in ensuring a regulatory platform for development, approval, marketing, and maintenance of products. Our services comprise regulatory consulting on product development and maintenance of marketed products and services within quality assurance.



Jeannette Kræmer  
Director of Quality Assurance  
and Regulatory Affairs

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## Technical Services

At aCRONordic we meet an increased demand for expertise on updated technologies for clinical trials. IT tools clearly should make life easier while simultaneously securing data. Flemming Goldbach, (M.Sc Business Adm. and Computer Science) is an expert in exploring and making the most of new and advanced technology – and was appointed Director of Technical Services in August 2008. aCRONordic provides services to customers with updated technologies in Technical data management, Statistical programming, and GCP hosting. We offer our assistance in application of the CDISC standards required by regulatory bodies for electronic submissions. We offer consulting on GCP computer system validation, host Oracle Clinical, EDC, and Pharmacovigilance systems in adherence to CDISC data standards.



Flemming Goldbach  
Director of Technical Service

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## aCRONordic strengthens position in Finland

As of 08 September aCRONordic opened its office in Espoo, just outside Helsinki. Anneli Vuorinen (RN) took the new office in use on the same day joining as Team Leader of Clinical Operations in Finland. Anneli Vuorinen brings extensive experience, leadership, and professionalism with her from working more than 13 years in the pharmaceutical industry in Clinical Operations.

She has thorough insight in all aspects of the operational parts of clinical research, experience as a manager, and in addition she has acted as a teacher and mentor for a number of years. Anneli is joining aCRONordic from MSD Finland Oy, where she was a Territory Research Manager. She will build the organisation in Finland, based in the new aCRONordic premises in Espoo.

As the CRO market leader in Denmark, aCRONordic is now implementing the same unique and innovative business model for Clinical Operations in the Nordic area, providing the same high level of quality services to customers here - as is the standard in aCRONordic.

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