

2009 has been a challenging year where both aCRONordic and our many customers have been affected by the financial crisis. aCRONordic has chosen to fight the crisis by focusing on the future, ensuring we have a broad business base both in Denmark and the Nordic region, and that we continue to build our development CRO business areas. We aim to use our broad spectrum of competences to partner with customers developing regulated life science products throughout the entire development process.

At the end of May we will be running an Oncology Training Programme in Uppsala where we will train participants in the special conditions required when doing clinical trials in Oncology. You can read more on www.aCRONordic.com.

This issue of aCRONordic News focuses on our newest business initiative, the aCRONordic Research Clinic. By focusing on study efficiency and proactive patient recruiting, and with a staff that is 100% dedicated to clinical studies, aCRONordic can help our customers reduce cost and time to market while taking steps to ensure continued drug and device development in Denmark.



Soren Strøh
CEO and founder of aCRONordic

aCRONordic Research Clinic Keeping Drug Development in Denmark



On 14 January aCRONordic opened the doors to a new research clinic that designs and conducts out-patient clinical trials for pharmaceutical and medical device companies as well as for other companies with health claim products.

Professional Staff Focused on Quality

The clinic is staffed by experienced doctors and nurses who ensure the trials are run at the highest quality level, and that they live up to ethical standards. Running clinical trials is aCRONordic's main business area, which means that the aCRONordic staff is experienced in working within the GCP system and that they devote the time required to ensure adherence to study protocols and resulting in reliable data.

Proactive Patient Recruitment

One of the big challenges in running successful clinical trials is timely patient recruitment. The staff of the aCRONordic Research Clinic invests extra energy in ensuring the right number of patients with the right profiles is available in order to complete the study on time. This is done through feasibility studies, focusing on eligibility criteria, careful planning and constant focus. The aCRONordic Research Clinic takes advantage of a wide variety

of recruiting channels, including internet media and subject databases.

Our professional staff puts an extra effort into screening potential test subjects by phone to ensure that those who actually come to the clinic are patients who meet the eligibility criteria. "This high quality screening process has been a real time-saver for the doctors in the clinic. Think, we don't have to spend time talking to patients who are out of scope," says Mads Engelmann, chief investigator and head of the clinic.

The combination of proactive patient recruitment and focus on reliable data

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News from the FDA

The FDA is considering changing the Medical Device approval process, requiring clinical trials for a broader group of products. They are currently conducting a comprehensive study of the process – and in February a public hearing was held. In the next issue of aCRONordic News we will focus on the Medical Device approval process in both Europe and the US and report on the progress of the study.

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means improved study efficiency, reduced cost and shorter time to market.

Continued Drug and Medical Device Development in Denmark

Many clinical trials take place at hospitals, but the demands on Danish hospital doctors continue to increase, and it can be difficult for them to give high priority to clinical trials. At the same time many trials involve recruitment of subjects with no other reason to go to a hospital. Since speed is essential in drug development, there is a high risk of clinical trials and drug development being moved to Eastern Europe and Asia. The aCRONordic Research Clinic is 100% dedicated to running trials and can take on trials with subjects not in the hospital environment. This could mean that more drug development can take place in Denmark, ensuring that Danish doctors and hospitals have the necessary knowledge of and practical experience with new and up-coming drugs. The Danish pharmaceutical companies and the pharmaceutical affiliates in Denmark have the advantage of being able to work with a research clinic nearby.

Functional Foods and Other Health Claim Products

Clinical trials are most often associated with the development of drugs and medical devices, but the aCRONordic Research Clinic can also contribute to the testing of functional foods and other health products where there is a need to demonstrate the effects of the products.

The First Study

The new aCRONordic Research Clinic has now embarked on its first study, a vaccine study for the State Serum Institute (SSI), which is testing an all-in-one vaccination against tetanus, diphtheria and whooping cough. The study will involve a total of approx. 800 healthy volunteers over the age of 18. When asked how it is going with patient recruitment, Mette Kaltoft-Sørensen, Project Coordinator and Leading Study Nurse breaks into a broad grin: "When we opened the clinic on the very first day, we had already received nearly 72 e-mails and 26 phone messages from interested test subjects. And that is how it has been ever since. We have had to involve extra personnel to man the phone and answer e-mails. So how has it gone?"

Super! Our intensive planning seems to have paid off."

Staff of the aCRONordic Research Clinic

Mads Engelmann

BSc, MD, PhD Chief Investigator



Mette Kaltoft-Sørensen

RN Project Coordinator and Leading Study Nurse



Lack of Time is the Main Barrier for Running Clinical Trials in Denmark

The Capital City Region (Region Hovedstaden) has published a report that evaluates the region's efforts at becoming a bio-health cluster, the challenges it faces in the area of clinical research, and how its competitiveness can be strengthened.

According to the report the main barrier for running clinical trials in Denmark is that hospital doctors do not have enough time to prioritise clinical trials: the hospital sector is not prepared to act quickly when contacted by researchers. At the same time what matters most to the drug industry is speed: how quickly the trials can be set up and run.

Denmark has many advantages that make it a unique partner for the drug industry

and have a history of a high number of clinical trials per inhabitant. Some of the advantages identified include:

- Talented, internationally recognized researchers
- Highly developed data registration system i.e. the CPR register
- Tracking of health problems and socio-economic conditions
- High level of reliability, dependability and trustworthiness
- High willingness amongst the Danes to participate in clinical trials

The report points at the importance of having a well-functioning infrastructure. It is the experience of drug researchers that Danish hospitals do not have the space or the facilities required for research. Since

there is a tendency towards treating large groups of chronic diseases e.g. diabetes and COPD in private practices instead of hospitals, there is a risk that there will be less research in these very common diseases.

Clinical research is critical for Denmark's ability to develop an efficient, high quality, modern healthcare system, as it contributes to being able to identify the correct treatment for the individual patient. Clinical research is an absolute necessity for the drug industry to be able to continue to develop new products and bring them to market. It is important that Denmark maintains its leading position within clinical research and prevents the stagnation in number of clinical trials taking place in Denmark.