

aCROnordic has embarked on 2009 with exciting projects and plans to work with. Already this month we offered a course in the operational challenges of clinical trials in oncology, sharing our expert knowledge and insight with customers with particular focus in this area. More courses are planned in the future and our website [www.aCROnordic.com](http://www.aCROnordic.com) is where you may keep yourself updated on this – or even sign up for an alert on news and courses.

Our quality services are readily available in Finland, where the organisation now counts four people, with broad and long experience in clinical operations. Furthermore the business is steadily growing as we are now opening our own office in Stockholm, to improve the service to our Swedish customers.

This issue of aCROnordic News focuses on data standardisation and proposes CDISC (Clinical Data Interchange Standards Consortium) an important subject to follow for companies in the business of conducting clinical development. aCROnordic has a number of services to offer in relation to CDISC. Please find more information in aCROnordic News Issue 2.

*Søren Strøb*  
CEO and founder of aCROnordic



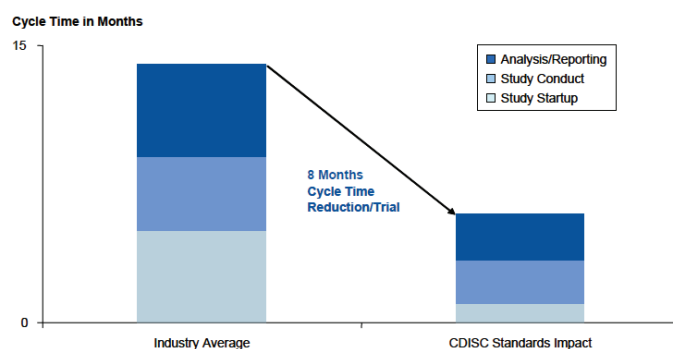
Søren Strøb,  
CEO and Founder

## Data standardisation is cost saving by common sense

Due to the repetitive nature of clinical trials, standardisation is common sense. It saves time and thus it saves money. This is also true for data standardisation. Standardising data ensures efficient data exchange, and improved work flows. Errors are potentially prevented; data consolidation is made easier and more consistent. Standardised data processing will improve data quality and result in considerable cost savings. In short the merits of data standardisation comprise:

- **Increased data quality**  
- A familiar CRF reduces the number of errors and improve the work flow
- **Significantly faster trial setup**  
- Re-use of standardised CRF modules decreases the amount of time needed for trial setup and testing
- **- and trial termination**  
- The statistical programming can be re-used from one study to another, leaving time to focus on analysis
- **Improved and eased consolidation of safety and efficacy data**  
- This regulatory requirement for safety data, is almost readily achieved through standardisation of data across trials  
- Between partners during sales processes and due diligences
- **Efficient data exchange**  
- From CRO's and other suppliers
- **Shorter assessment time with regulatory authorities**  
- Data standardisation may in the future reduce the assessment time as no time is wasted to format the submitted data

Conclusively, pharmaceutical businesses, biotech, and medical device companies undertaking clinical trials can profitably standardise their clinical study data. The question is then which data standardisation to choose. aCROnordic is convinced of the benefits of CDISC.



Source: Gartner, November 2006

## CDISC – What is it?

The CDISC (Clinical Data Interchange Standards Consortium) started in 1997 as a special interest group and was formally established as a non-profit organisation in 2000. The CDISC initiative has had great momentum in the past few years. Today more than 200 organisations in the pharmaceutical and biotech business, CRO's, vendors of technology, academic institutions, and authorities back up this initiative as members of the consortium.

*"The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare"*

### Regulatory implications

A uniform data format like CDISC eases the evaluation of regulatory files for marketing authorisations. An essential driver for CDISC is an endorsement from the FDA, which

has now formally announced that the preferred data standard to be used in New Drug Applications is CDISC. The EMEA has not affirmatively endorsed one data standardisation system over the other, however, in general the idea and benefits of data standardisation are acknowledged also in Europe.

### Benefits from CDISC

The CDISC initiative aims for global standardisation of storage and exchange of clinical trial data. This will improve and optimise work flows for all companies working with clinical trial documentation. It is effective and quality assurance is implicit. CDISC data standardisation establishes overview as well as insight into current and previous clinical trials. The CDISC uniform format enables comparisons across trials.

Read more about CDISC:  
<http://www.cdisc.org>

## aCRONordic 's expertise within CDISC

aCRONordic has worked with data modelling and data standardisation since 1998. As a member of CDISC we have continuously worked towards implementing the CDISC standards. Trial data are stored in our clinical data model, which is based on the CDISC standard, i.e. we deliver clinical data in CDISC format. Furthermore, we offer services to customers who need to transform existing clinical data into CDISC format.

We have a standardised procedure and methodology for migration of legacy clinical data to CDISC and on top of that hands-on experience with carrying these milestone projects through for our customers. We offer consulting, training, and implementation of the data format.



Umair Ijaz Dar  
CDISC Consultant



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To learn more about how CDISC can improve your data management system, please contact:  
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## aCRONordic Sweden

As a further expansion of aCRONordic 's activities in the Nordic area the company now opens its own office in Stockholm, Sweden. Inga-Stina Ödmark, RN and PhD, is joining aCRONordic and will head the office.

- Inga-Stina is a true resource of experience and insight in clinical operations. In addition to her strong personality and positive attitude, I am confident that she will provide quality services and add value to our Swedish customers, says Claes Strøm, COO, aCRONordic.

Inga-Stina has a strong track record and extensive experience from working 22 years in the pharmaceutical industry primarily with clinical operations and as a sales specialist.

She is knowledgeable in a wide range of therapeutic areas covering gynaecology, psychiatry, nephrology, neurology, general medicine, and cardiovascular diseases.

Inga-Stina received a medical PhD degree in 2004 at the University of Umeå for her research.

Inga-Stina joins aCRONordic on 20 April 2009.

If you want to know more about aCRONordic services and offers within clinical operations, please contact [Claes.Strom@acronordic.com](mailto:Claes.Strom@acronordic.com), tel: +45 4516 8814