

The increase in therapeutic choices has raised the interest and need for data describing the comparative effectiveness of the given medicinal alternatives. Issue 3 holds a feature article on the international GRACE (Good ReseArch for Comparative Effectiveness observed) principles. We invite you to learn more on how to overcome the methodological challenges of observational studies.

We have recently launched our new aCRONordic EDC, which is based on the Oracle RDC platform. I am confident that users of Oracle Clinical will appreciate the EDC user friendliness combined with the traditional setup of studies using Oracle Clinical. We are happy to offer this improved EDC to our customers.

aCRONordic has developed standard oncology modules for our EDC to increase the speed and data quality in the oncology trials we manage. We are currently making use of the standards in an investigator initiated trial at Århus and Herlev Hospital. This leads me to highlight, that aCRONordic is a competent partner also for investigator initiated trials. We provide the services and resources that investigators often lack in their own organisations such as data management, EDC, submission services, and pharmacovigilance. Our services support the investigators to overcome the hurdles of running GCP trials, meet the deadlines, and deliver important clinical data that can be used with regulatory agencies around the world.



Søren Strøb
CEO and founder of aCRONordic

Good Practice for observational studies

Real life data are increasingly acknowledged for contributing to the hierarchy of clinical evidence. The commitment from the pharmaceutical industry lies in complying with good practice in order to ensure data validity. The GRACE principles are the guidelines to follow and were updated in July 2009.

The GRACE principles (Good ReseArch for Comparative Effectiveness Observed) were updated in July 2009. They describe a hierarchy of evidence for observational research on comparative effectiveness that can be used by decision makers. "Observational studies are investments just like any other clinical study. The point is to ensure the return on this investment, and to get a scientifically valid and clinically useful output of your observational study," says Mads Engelmann, Chief Medical Officer, aCRONordic.

Fill the data gaps

Randomised clinical trials (RCT) yield the highest quality of clinical evidence, but rarely RCT provide direct comparisons of the many different treatment options that are available. Furthermore RCT have a highly selected population. Hence the data give little guidance for the prescribing physician on clinical decision making in real life, where patients are rarely selected at all.

Due to the international commitment on improving standards for observational studies, the value of observational research models is increasingly appreciated by many regulatory and advisory bodies involved in healthcare resource decision making. Still, the methodological challenges must be addressed to facilitate meaningful analyses and reliable interpretations.

Build the evidence

The GRACE principles hold the key elements for good practice. They describe

how to define research questions and methods upfront. How to collect valid, clinically relevant data and analyse, interpret, and report the data. Furthermore they describe how to analyse sensitivity and encourage searching carefully for alternative explanations for the study results.

"As human beings we naturally get excited when our hypotheses seem to be proven. Refraining from jumping to conclusions, and instead carefully searching and analysing the data for confounders are part of the commitment. This is where the observational study earns its right as being serious," says Mads Engelmann.

Improving the standards

He highlights that the guidelines are beneficial for all parties involved in observational studies: "It is hardly ethical to bother patients to participate in a clinical study, where the results end up being biased or a clinically meaningful interpretation is impossible. You need to ensure that the effort is worthwhile for the sponsor, the investigator, and most certainly also for the patient," says Mads Engelmann.

Learn more about the GRACE principles

For more information on the GRACE principles and Clinical Research consulting contact Mads Engelmann, tel: +45 4516 8854. Mads.Engelmann@aCRONordic.com

Visit also the GRACE principles website: <http://www.graceprinciples.org/index.html>

New aCRONordic EDC launched in oncology study

The new aCRONordic Electronic Data Capture (EDC) was recently launched in an investigator initiated trial in oncology at Århus and Herlev Hospital.

“We are very pleased about this new EDC. It is a major step forward for our customers on data management. It enables lean and improved working processes with more efficient resource

use and better data quality,” says Søren Strøh, CEO, aCRONordic.

With the latest release the Oracle RDC platform is now performing satisfactory. With this addition aCRONordic can now offer the upside of working in a fully integrated (Oracle) data management environment. It has standard modules for oncology, improved functionality,

and it is CDISC compliant. Furthermore the Oracle system ensures that the aCRONordic EDC lives up to regulatory standards and requirements.

Read more about EDC Technical Services and EDC at our website under Our CRO Services <http://www.acronordic.com/acronordic/subpage3.aspx>



Karen Rysgaard has joined aCRONordic

As of 01 June Karen Rysgaard, MSc Pharm was appointed Director, Clinical Operations at aCRONordic.

- With the combination of her broad experience in the industry, leadership skills, and insight into clinical operations, I am confident Karen will drive and grow the business competently, says Birgitte Guldhammer, President, aCRONordic. Karen Rysgaard has fifteen years of experience in Clinical Operations and Drug Development from all parts of

the pharmaceutical industry, including pharmaceutical and biotech companies, and contract research organisations. She joined aCRONordic from Norma, where she was head of the Nordic and Baltic team.

Karen Rysgaard is taking on the responsibility of optimising Clinical Operations routines and sharing of best practice across borders. Hence aCRONordic Clinical Operations in Denmark, Sweden, and Finland are now reporting directly to her.

