

Northern lights

No one in the pharmaceuticals industry today is in doubt that time is the most scarce resource in clinical development. However, to make the most of yours, you don't want to put study quality at risk. For this reason, the Scandinavian countries have been among the preferred regions for conducting clinical trials for decades. **Nordic & Baltic Medical Advisers (NORMA)** tells *World Pharmaceutical Frontiers* just why Scandinavia leads the way in clinical research.

Susanna, the head of the trial team, was anxiously walking down the corridor to meet the vice president of global development. This morning an email from Peter in data management had really made a bad start to the week:

"To a large extent, data on the pivotal study on the compound PhamI144, which is expected to be the next blockbuster of BIGPHARMA Inc, were jeopardised because the tracking of patients was lost. The issue was that subjects included in the study had been registered in the Clinical Report Forms (CRFs) under the same set of initials: AJ, PHS, SFE. This morning, it was impossible to consider the full impact of damages, but an unacceptable delay was inevitable..' Running down the hallway to her meeting, Susanna could already imagine the response of the VP: *"How could this happen? How will you avoid this from happening again? I need answers, and I need them fast..."*

Scandinavia has a well-established tradition for clinical research: major milestones in the treatment of chronic diseases such as asthma and diabetes are rooted in the scientific culture here. Lately 'spin-offs' from this have created dynamic centres for oncology research in the Oslo Cancer Cluster in Norway and in more than 100 ongoing projects in The Medicion Valley (Southern Sweden and Eastern Denmark). There is also the internationally renowned Karolinska Institute in Stockholm, Sweden.

The region has 30 million inhabitants, who are served by 570 hospitals, of which 44 have status as university hospitals. At all these sites you will find access to a huge group of specialists covering many fields (see table).

“ Major milestones in the treatment of chronic diseases such as asthma and diabetes are rooted in the scientific culture here ”

Following procedure

Filing submissions to ethical committees (ECs) in the different countries is no more difficult than filing on either side of the Channel – NORMA would argue sometimes even easier, since attitudes are similar throughout Scandinavia. Skilled clinical research organisations (CROs) will guide you in picking your primary investigators at sites to facilitate the most proactive discussions with the EC.

As long as you communicate in English, language will not be a problem; patient information will need to be translated, but other than that you will easily find your

Specialists in Scandinavian countries

Specialists in Nordic countries	Numbers
Cardiovascular	3,340
Dermatology	1,640
Psychiatry	8,100
Gastroenterology	1,581
Endocrinology	935
Oncology	1,378
Neurology	2,254
Paediatrics	7,183
Gynaecology	6,188
Haematology	1,132
Infection	1,143
Ophthalmology	2,664
Immunology	1,151
Rheumatology	907
Urology/Nephrology	1,835
Internal Medicine	2,312
Surgery (various)	1,360
Occupational Health	1,292
Otolaryngology	163
Radiology	258
Anaesthesiology	366

Source: NORMA analysis 2010

way around. Fee structures are made very transparent, the underlying principle being that as a sponsor you will pay only for actual costs incurred. Most hospitals are publically owned, and the Nordic governments make it a priority to strengthen life science research. As a consequence, overheads will cover administration and you will not be charged for aesthetics.

Last but not least, the healthcare systems in each country assign a unique number to each individual citizen. This number is constant throughout the person's life and prevents any kind of mix-up. Maybe Susanna will suggest to her boss that the next part of the clinical programme should be moved to Scandinavia.

Further information

NORMA
www.norma-cro.com, www.norma.dk

