



Hva kan Norge lære av Danmark – fra et industriperspektiv?

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Current status from a Novartis perspective

Norway is characterized by a high density of high level Medical Experts and by a well-developed collaboration with HA/EC and a well-organized health care systems

Novartis run quite a lot of trials in Norway (currently more patients enrolled than in Denmark)

Norwegian medical experts are used as consultants in several of our R&D projects

In particular there have been close collaborations in reumatology, transplantation, neurology, cardiovascular and oncology.

On a global scale the basics are quite similar in NO/DK

Attracting clinical trials is a global competition and the Nordics have been challenged over the last years

New initiatives in Denmark seem to have increased allocation of trials

Agenda

1. Why and how are Denmark succeeding in attracting industry trials?
2. What are the most important factors in country selection for a company like Novartis?
3. What can be done (in Norway) to be more attractive for industry trials?

Why and how are Denmark succeeding in attracting industry trials?

- **Structure of healthcare system**
 - Research is integrated in healthcare system
 - Centralized and highly specialized units
 - Research interested medical experts
- **Political focus**
 - Clinical trials benefit society
 - Proactive approach
- **Trust/Collaboration**
 - Private/public collaboration is encouraged (and accepted) - dialogue
 - Public perception is generally very positive (Clinical trials is a benefit to all)
 - Clinical trial networks, NCI role
- **Operational framework/infrastructure**
 - Dedicated resources in the public sector to facilitate clinical research
- **Specific initiatives (NEXT, Clinical Trials Office, etc.)**

Two public initiatives

- NEXT
 - Public/Private partnership
 - Involves all stakeholders
 - Common goal – **Improve framework in Denmark!**
 - Kickstart
 - Governance/ balanced funding / risk sharing
 - Report on economic and quality benefits to the society/healthcare system
- Clinical Trials Office Denmark
 - Improve interface between healthcare system and research projects/companies
 - Common standards (legal/contracts etc.)
 - TA specific research networks (one point of contact)

What are the most important factors in country selection for a company like Novartis?

Key points – Global competition

- Medical expertise
- Clinical trial experience – Track Record
- Quality
 - GCP
 - Protocol adherence
 - Health authority/Ethics committee competence/experience
- Speed
 - Start up times
 - Feasibility/contracts
 - Patient recruitment
- Reliability
 - Commitment and patient recruitment
- Price

What can be done (in Norway) to be more attractive for industry trials?

Key points

- Strategic

- Integrated strategy from all stakeholders (common goals)
- The healthcare system is also about innovation
 - Incentivize medical experts to do or facilitate research (clinical research)
 - Direct and indirect benefits from clinical trials
- Focus on strengths and opportunities
 - Examples: Secondary use of anonymized data, Biobanks, Biotech clusters, Specialties with high level of medical expertise, Pre-Consent process
- Try to limit/avoid political micromanagement
- Don't compete within Norway (maybe we should not compete within the Nordics?)

- Operational

- Transparent processes
- Legal Framework
- Centralized negotiations
- Networks – locally and globally
- Quality in Feasibility (invest in feasibilities)