

Nordic Trial Alliance

*Nordic Conference on Pediatric Medicine
(Helsinki 08.10.19)*



Ole Alexander Opdalshei
The Norwegian Cancer Society/Nordic Trial Alliance

Why are patient organizations interested in clinical studies?



«Current evidence suggest that there is an association between the engagement of individuals and healthcare organisations in research and improvements in healthcare performance» (Boaz et al, BMJ Open 2015)



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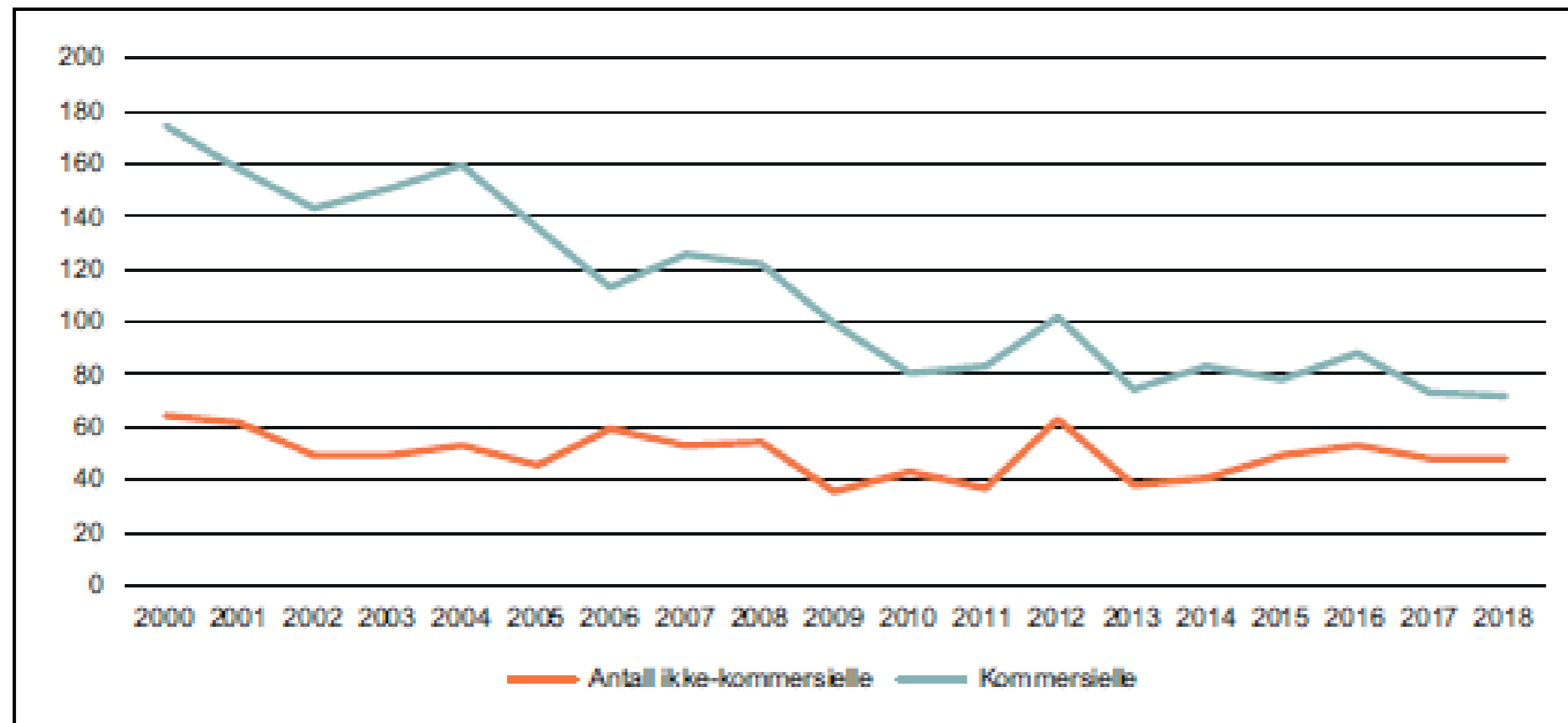


How does clinical research improve healthcare outcomes? (Krzyzanowska et al, Annals of Oncology 2011:22)

Type of benefit:	Patients in research-active sites	Research-active institutions	Society or health care system
Infrastructure:			
Access to new treatments / rollout of new technologies earlier or more widely	X	X	X
Establishment of expert teams and centres of excellence for testing and delivery of novel interventions	X	X	X
Frequent updating and training of staff	X	X	
Processes of care:			
Changes in group and individual behaviour, including:–more rapid uptake of newer treatment strategies and technologies–adoption of evidence-based guidelines	X	X	
Especially close monitoring and clinical Support	X		
Other:			
Knowledge generation			X
Reduction in healthcare resource use or cost by demonstration of ineffective or unnecessarily costly interventions		X	X
Wealth generation:–strengthened local pharma/biotech R&D–income to health systems/academia from licensing intellectual property – ideally reinvested into patient care/further research		X	X
Reduction of academic/clinician ‘brain drain’		X	X
Patient & clinician sense of contributing to improving care for other/future patients	X	X	X

Mens de venter på godkjenning av nye og dyre medisiner, starter sykehusleger studier for å gi pasientene den beste behandlingen

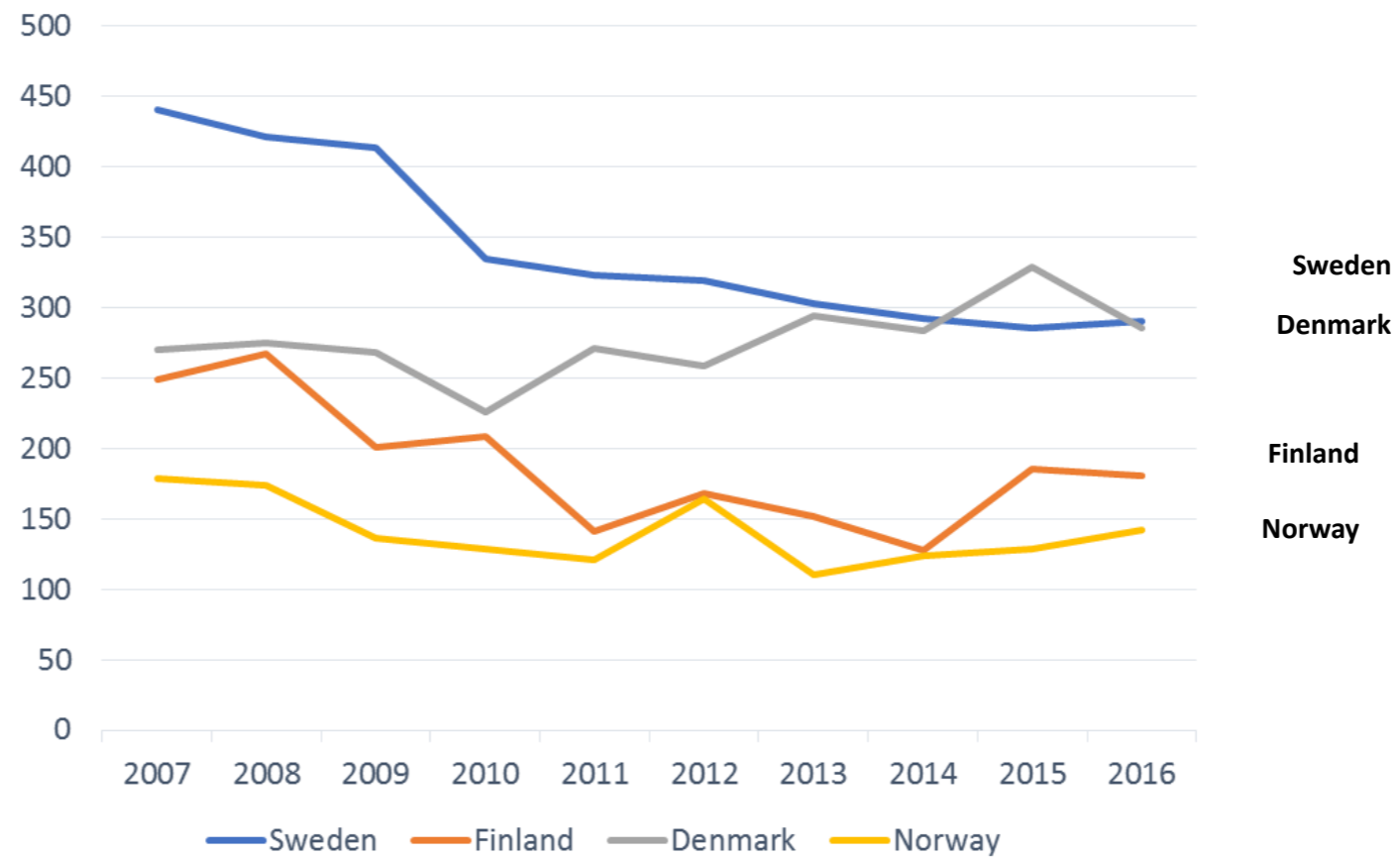
Som deltager i en forskningsstudie får lungekreftpasient Naveed Ali behandling med en dyr medisin som ennå ikke er godkjent i Norge. Dette er snarveien leger nå tar i bruk for å hjelpe pasientene sine.



Figur 8.4 Antall søkte kliniske studier fordelt på sponsor

Kilde: Statens legemiddelverk

The total number of Clinical Trial Applications to Regulatory Authorities in the Nordics



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Why the Nordic Trial Alliance Project?

- Earlier trend with declining number of clinical studies in all Nordic countries
- Complex regulatory situation = difficult for academic studies
- Companies have difficulties finding researchers / trial sites
- Barriers impeding academia-industry-collaboration
- Nordic patients don't know how to find on-going clinical studies
- Lack of project funding for Nordic projects
- Barriers for recruitment of patients cross borders



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The Nordic Trial Alliance

Aim

- to strengthen clinical research in the Nordics, and especially clinical multi-centre trials

2013-2016

- Activity under the “Sustainable Nordic Welfare”
- Funded by Nordic Council of Ministers and NordForsk
- Hosted by NordForsk

2017-2019

- Towards personalised medicine
- Funded under the Norwegian priority project “Nordic Cooperation for better health”

<http://nta.nordforsk.org>



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Aims of NTA 2.0 – personalised medicine

- Facilitation of clinical study cooperation between clinics and research groups in the Nordic countries, and between clinical environments, academia and industry
- Increasing the knowledge of opportunities to participate in studies among patients and their attending physicians
- Identification of hindrances and bottlenecks that impede clinical research
- Increasing access to clinical infrastructure across the Nordic countries
- Sharing experience and expertise in clinical trials on **personalised medicine**
- Facilitation the use of **clinical quality registers and real world data** in clinical research



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The NTA Steering Group

- Ole Alexander Opdalshei, Norwegian Cancer Society, Chair
- Mia Bengtström, Pharma Industry Finland
- Pierre Lafolie, Swedish Ethical Review Authority
- Mef Nilbert, Danish Cancer Society Research Center
- Kristján Erlendsson, Iceland
- Marika Greberg, Clinical Studies Sweden



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NTA activities

- 1. Establish a NTA website**
- 2. Stakeholders meeting**
- 3. Funding of pilot projects**
- 4. Funding of strategic projects/strategic workshops**
- 5. Funding of project in paediatric cancer research**



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1. The NTA website

- Information and links to national clinical research initiatives, trial units/sites and networks (researchers, companies, patients)
- Clinical trials explained
- Information on on-going/recruiting clinical studies in the Nordic countries
- News
- Main target groups: researchers and companies



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2. NTA Stakeholder Meetings

- Stakeholder meetings with targeted focus:
 - *Identified areas in immediate need of strengthened clinical research infrastructure cooperation (2013)*
 - *Norden as a common clinical research area (2014)*
 - *Nordic cooperation on ethical review procedures (2015)*
 - *Potential in Nordic clinical research cooperation (2016)*
 - *Towards personalized medicine in Nordic clinical trials cooperation: NTA 2.0 (2017)*



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3. NTA Pilot Projects 2014

- **Nordic Arthroplasty Register Association**
 - an international quality register study of total joint arthroplasty of four nations (PI Keijo Mäkälä, FIN)
 - **Assisted reproductive technology (ART) and safety in the Nordic countries**
 - the Committee of Nordic ART and Safety (PI Anja Pinborg, DK)
 - **NordStar**
 - the most effective treatment strategy in early rheumatoid arthritis comparing four different treatments (PI Merete Hetland, DK)
 - **BMT (bone marrow transplantation) in elderly AML (acute myeloid leukemia)**
 - a prospective, controlled, international study (PI Mats Brune, SE)
 - **Discontinuation of infliximab therapy in patients with Crohns' disease during sustained complete remission** (PI Mark Ainsworth, DK)
-
- Total budget 16 MNOK
 - Projects funded with 2-4 MNOK each
 - Some projects completed, some still ongoing



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4. NTA strategic projects 2016/17

- increasing Nordic collaboration by reducing cross-border barriers

- 1. Workshop on Cross-border Participation in Clinical Trials**
- 2. Harmonised Nordic Ethical Evaluation of Clinical Trials**
- 3. Nordic Conferences on Real-World Data**
- 4. Establishing a Nordic Network for Clinical Trials in Children –stage II**
- 5. Nordic Hotspot for Life Science**
- 6. Nordic Monitoring Network**
- 7. Nordic Network on antimicrobial multi-resistance research**
- 8. Nordic conference on pragmatic clinical trials**



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4b. 2019: NTA funds six strategic networking arenas (aim: enhance Nordic clinical research cooperation)

Strategic workshop of the borderline research between traditional interventional clinical trials RCT and Real-World Evidence/Register studies

Nordic Alliance in Faecal Microbiota Transplantation (FMT) - Christian Lodberg Hvas (Aarhus University Hospital)

Nordic network for emergency department pain management

NORdic uroTHElial cancer REsearch Group – NORTH-REG - Jørgen Bjerggaard Jensen (Aarhus University Hospital)

Nordic Anal Cancer Network

EUPATI Nordic Workshop - Mirjami Tran Minh (Association of Cancer Patients in Finland & EUPATI Finland)



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5. Call for Nordic Projects on Paediatric Cancer Research 2018

- Cofunded by the Norwegian Cancer Society, the Norwegian Ministry for Health and Care Services, Research Council of Norway and NordForsk
- To support Nordic researcher projects in cancer medicine or expansion of ongoing national projects into Nordic ones
- Establish Nordic competence networks within clinical research on paediatric cancers
- 38 MNOK total budget
- Deadline September 2018
- Three projects funded with up to 10 MNOK each



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Nordic Projects on Paediatric Cancer Research 2018

Nordic ALLSTAR

Project Leader: Thomas Leth Frandsen, Rigshospitalet, Copenhagen
(DK-FIN-NO)

NOPHOMatch

Project Leader: Karsten Nysom, Rigshospitalet, Copenhagen
(DK-FIN-NO-SE)

ALLTogether - a European treatment protocol for children and young adults with acute lymphoblastic leukaemia (ALL)

Project Leader: Mats Heyman, Karolinska University Hospital,
Stockholm
(ALL Nordic countries)



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NTA stakeholders meeting autumn 2019

- Strategic workshop focusing on promoting Nordic collaboration on paediatric cancer
- Kick-off for the three pilot projects
- Platform for cooperation between
 - clinical research environments
 - academia-industry cooperation
 - discuss important topics connected to paediatric cancer (side-effects, new treatments etc)
- Platform for potential funders of Nordic research cooperation



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Activities 2019/2020

- Annual stakeholders meetings, conferences and workshops
 - Lessons learned workshop gathering all projects
- Support of Nordic network activities aiming to fulfill NTA aims
- Development of the NTA website
- Sustainability of NTA
- New activities will be announced on the NTA website



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- » Research priorities
- » Awarded Grants
- » **Application**
- » Reports

Nordic Cancer Union Research Grant

The Nordic Cancer Union (NCU) provides funding to support and stimulate collaborative cancer research within the Nordic countries. Researchers working in two Nordic countries or more must be involved in the project. The research project must be cancer relevant and uniquely suited to be carried out within the Nordic countries, and the effect of collaboration should be synergistic.

Funding is restricted to research that is in line with the [NCU's research strategy](#). The research strategy was adopted by the NCU Board on May 26, 2014.

NCU research grants are provided for one year. Further support for the project will require a new, yearly application. As a general rule, project funding can only be renewed twice; a project can obtain funding from the NCU for a total of maximum three years.

Read about the NCU's research priorities [here](#).

How to apply

Application deadline: 2 September 2019, 3 pm.

Please read the [Guidelines for NCU Research Grant Applications and Allocations 2019](#) before starting the application process here

Note that the electronic application form must be completed in English. [Apply here](#)

Please direct any questions to
Anne Mette Bak

FORSKNING

Vil ha felles etisk godkjenning av nordiske studier

Når en klinisk studie blir godkjent i ett nordisk land, bør godkjenningen også gjelde for de andre landene, mener Kreftforeningen.

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FOR HELSEPERSONELL

Derfor har Kreftforeningen tatt initiativ til en felles uttalelse fra de nordiske kreftforeningene.

– Det er viktig med felles nordiske kliniske studier innen kreftområdet, og vi ønsker at dette skal bli lettere å gjennomføre, sier Ole Alexander Opdalshei, assisterende

<https://nta.nordforsk.org/>

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