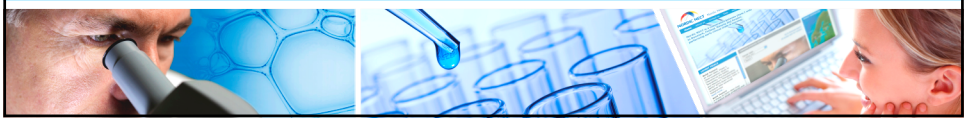
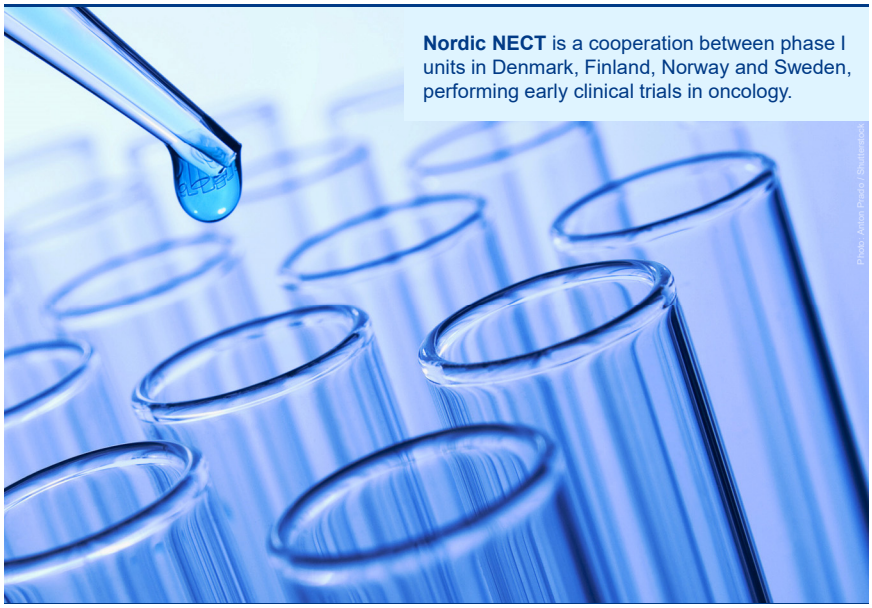
# Nordic NECT – Collaboration between Phase 1 Units

6th Conference on Clinical Trials in the Nordic Countries
25th Oct 2017

Katriina Peltola, MD PhD
Senior Consultant, Early Phase Trials
Helsinki

NORDIC NECT
Nordic Network for Early Cancer Trials





**Nordic NECT** is a cooperation between phase I units in Denmark, Finland, Norway and Sweden, performing early clinical trials in oncology.

## Nordic NECT

The network is designed to ensure patient access to new investigational drugs and to allow customer information and easy access to phase I and early phase II programs in the Nordic countries.

NORDIC NECT Nordic Network for Early Cancer Trials

**Patient access to investigational drugs**

Today, many seriously ill cancer patients do not have satisfactory standard treatment options leading to an unmet need.
We therefore need to facilitate enrollment to phase I and early phase II trials.

It is important to ensure the access to new investigational therapies. Patient recruitment is critical to the drug development program and pharmaceutical companies often choose tertiary oncologic centres with larger patient populations for initiating such trials.

Photo: Lasse Braun

NORDIC NECT Nordic Network for Early Cancer Trials

## Objectives

- To make the Nordic region more attractive for early clinical studies
- To perform state-of-art phase I and early phase II trials in oncology and hematology, to ensure the patients access to new investigational therapies
- To work for a bilateral agreement between the Nordic countries allowing for inclusion of patients in early clinical trial protocols across the borders
- To promote *"One point of entry"* for early clinical trials and common approval for the Nordic countries

NORDIC NECT Nordic Network for Early Cancer Trials

## NordicNECT was established in 2011

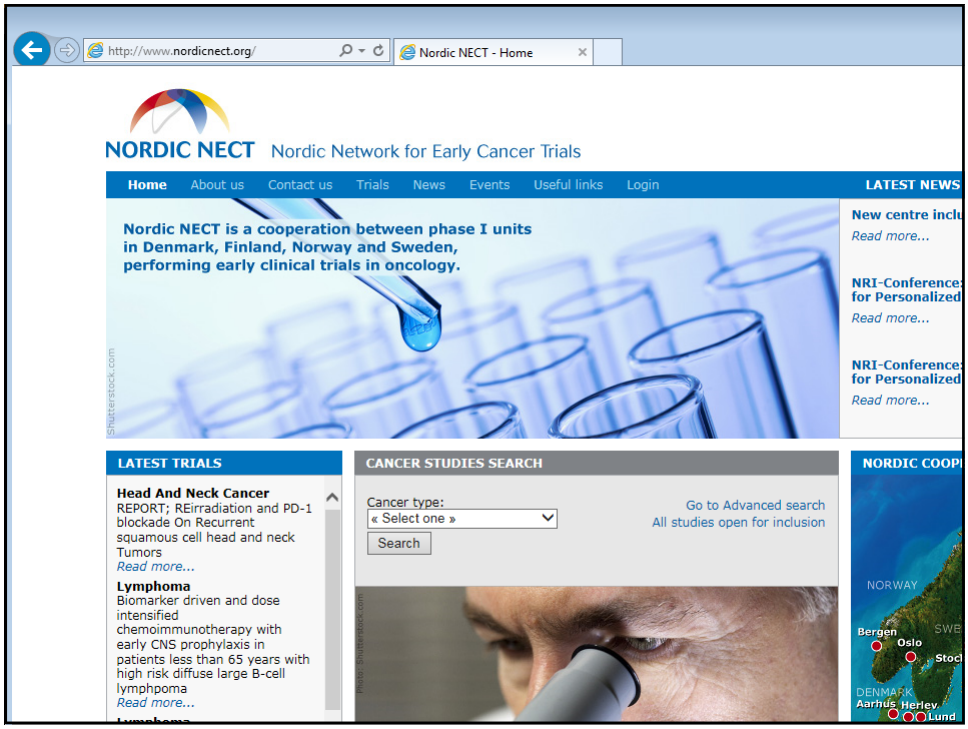
Main Structure:

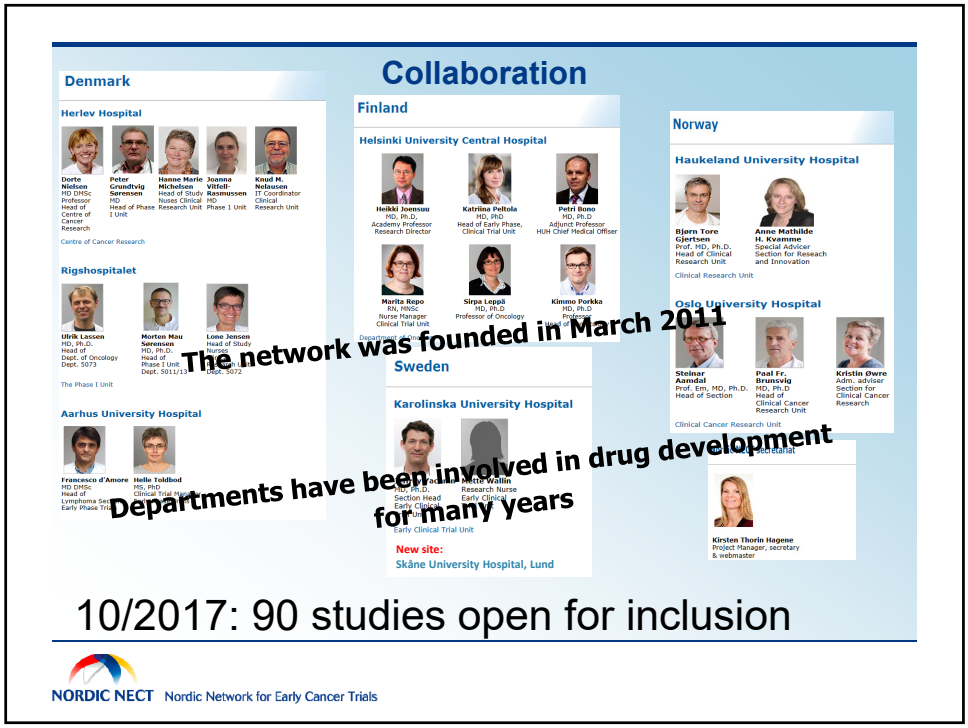
8 sites at the current moment. Members at each site are the ones conducting early phase trials (physicians,study nurses, study co-ordinaters, project managers, IT-staff)
The network is lead by the chair **Steinar Aamdal**.
Secretariat was established in August 2016 **Kirsten Thorin Hagene** as Project manager (50%). Two meetings annually.

Finance:

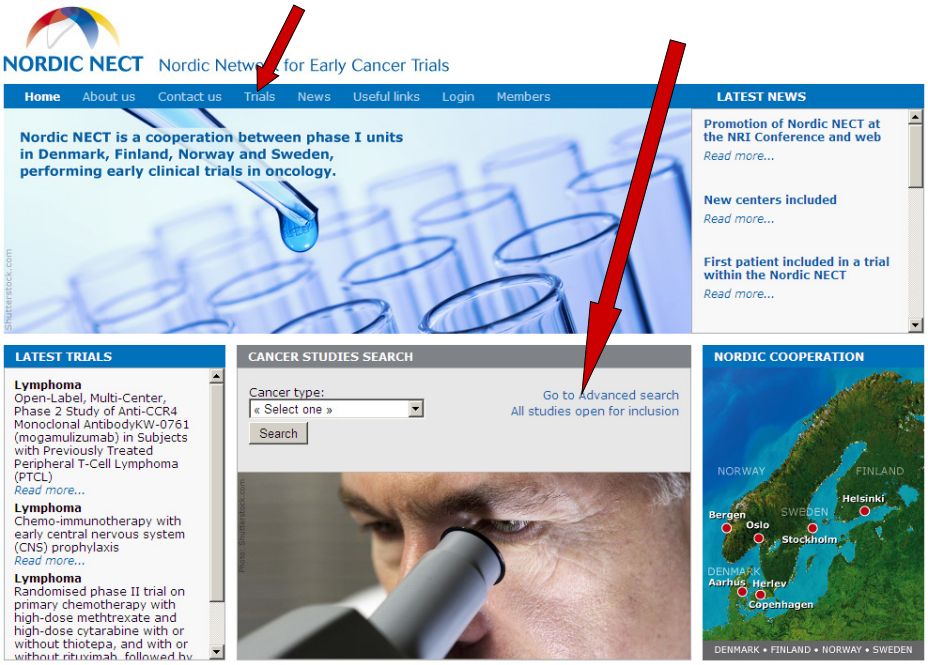
Nordic NECT web-site is supported by the Norwegian Cancer Society. Nordic NECT has also received additional funding from the Nordic Cancer Union and The Norwegian Radium Hospital Foundation.

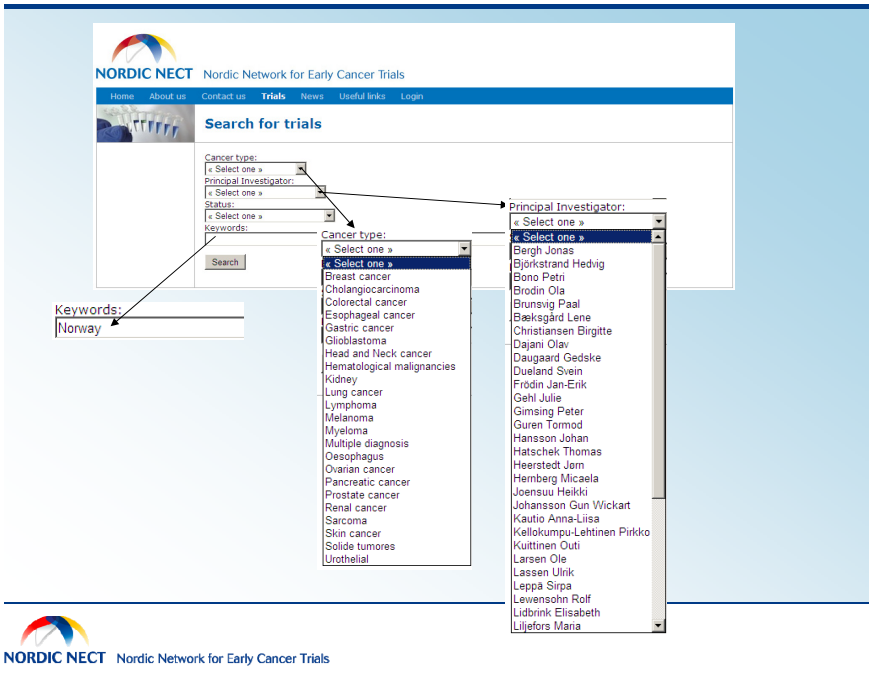
NORDIC NECT Nordic Network for Early Cancer Trials


http://www.nordicnect.org/
Nordic NECT - Home
NORDIC NECT
Nordic Network for Early Cancer Trials
Home
About us
Contact us
Trials
News
Events
Useful links
Login
LATEST NEWS
Nordic NECT is a cooperation between phase I units in Denmark, Finland, Norway and Sweden, performing early clinical trials in oncology.
New centre inclu
Read more...
NRI-Conference:
for Personalized
Read more...
NRI-Conference:
for Personalized
Read more...
LATEST TRIALS
Head And Neck Cancer
REPORT; REirradiation and PD-1 blockade On Recurrent squamous cell head and neck Tumors
Read more...
Lymphoma
Biomarker driven and dose intensified chemoimmunotherapy with early CNS prophylaxis in patients less than 65 years with high risk diffuse large B-cell lymphpoma
Read more...
CANCER STUDIES SEARCH
Cancer type:
« Select one »
Search
Go to Advanced search
All studies open for inclusion
NORDIC COOP
NORWAY
Bergen
Oslo
DENMARK
Aarhus
Herlev
Lund

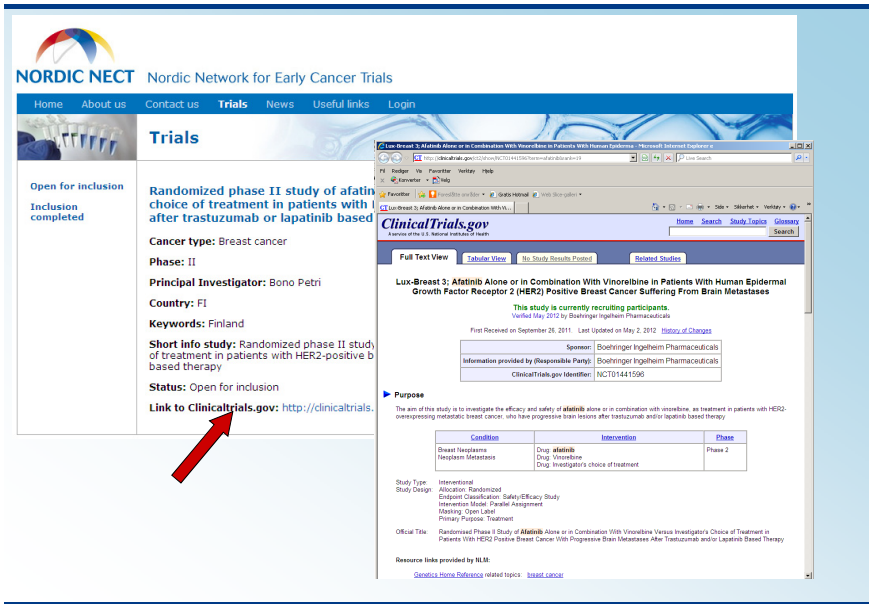

Collaboration
Denmark
Herlev Hospital
Centre of Cancer Research
Rigshospitalet
The Phase I Unit
Aarhus University Hospital
Finland
Helsinki University Central Hospital
Sweden
Karolinska University Hospital
New site:
Skåne University Hospital, Lund
Norway
Haukeland University Hospital
Clinical Research Unit
Oslo University Hospital
Clinical Cancer Research Unit
The network was founded in March 2011
Departments have been involved in drug development for many years
10/2017: 90 studies open for inclusion
NORDIC NECT
Nordic Network for Early Cancer Trials


NORDIC NECT
Nordic Network for Early Cancer Trials
Home
About us
Contact us
Trials
News
Nordic NECT is a cooperation between phase I units in Denmark, Finland, Norway and Sweden, performing early clinical trials in oncology.
LATEST TRIALS
Nordic NECT web
Search our data base
for new cancer studies:
www.nordicnect.org
NORDIC NECT Nordic Network for Early Cancer Trials


NORDIC NECT
Nordic Network for Early Cancer Trials
Home
About us
Contact us
Trials
News
Useful links
Login
Members
Nordic NECT is a cooperation between phase I units in Denmark, Finland, Norway and Sweden, performing early clinical trials in oncology.
LATEST NEWS
Promotion of Nordic NECT at the NRI Conference and web
Read more...
New centers included
Read more...
First patient included in a trial within the Nordic NECT
Read more...
LATEST TRIALS
Lymphoma
Open-Label, Multi-Center, Phase 2 Study of Anti-CCR4 Monoclonal AntibodyKW-0761 (mogamulizumab) in Subjects with Previously Treated Peripheral T-Cell Lymphoma (PTCL)
Read more...
Lymphoma
Chemo-immunotherapy with early central nervous system (CNS) prophylaxis
Read more...
Lymphoma
Randomised phase II trial on primary chemotherapy with high-dose methtrexate and high-dose cytarabine with or without thiotepa, and with or
CANCER STUDIES SEARCH
Cancer type:
« Select one »
Search
Go to Advanced search
All studies open for inclusion
NORDIC COOPERATION
NORWAY
FINLAND
SWEDEN
Helsinki
Bergen
Oslo
Stockholm
DENMARK
Aarhus
Herlev
Copenhagen
DENMARK • FINLAND • NORWAY • SWEDEN


NORDIC NECT
Nordic Network for Early Cancer Trials
Home
About us
Contact us
Trials
News
Useful links
Login
Search for trials
Cancer type:
« Select one »
Principal Investigator:
« Select one »
Status:
« Select one »
Keywords:
Search
Keywords:
Norway
Cancer type:
« Select one »
« Select one »
Breast cancer
Cholangiocarcinoma
Colorectal cancer
Esophageal cancer
Gastric cancer
Glioblastoma
Head and Neck cancer
Hematological malignancies
Kidney
Lung cancer
Lymphoma
Melanoma
Myeloma
Multiple diagnosis
Oesophagus
Ovarian cancer
Pancreatic cancer
Prostate cancer
Renal cancer
Sarcoma
Skin cancer
Solide tumores
Urothelial
Principal Investigator:
« Select one »
« Select one »
Bergh Jonas
Björkstrand Hedvig
Bono Petri
Brodin Ola
Brunsvig Paal
Bæksgård Lene
Christiansen Birgitte
Dajani Olav
Daugaard Gedske
Dueland Svein
Frödin Jan-Erik
Gehl Julie
Gimsing Peter
Guren Tormod
Hansson Johan
Hatschek Thomas
Heerstedt Jørn
Hernberg Micaela
Joensuu Heikki
Johansson Gun Wickart
Kautio Anna-Liisa
Kellokumpu-Lehtinen Pirkko
Kuittinen Outi
Larsen Ole
Lassen Ulrik
Leppä Sirpa
Lewensohn Rolf
Lidbrink Elisabeth
Liljefors Maria
NORDIC NECT
Nordic Network for Early Cancer Trials


NORDIC NECT
Nordic Network for Early Cancer Trials
Home
About us
Contact us
Trials
News
Useful links
Login
Trials
Open for inclusion
Inclusion completed
Cancer type
Title
Status
Country
Breast cancer
A phase Ib/II, multicenter, open-label study to evaluate the efficacy of AUY922 in combination with trastuzumab in patients with locally advanced or metasatatic HER2-positive breast cancer, that has progressed after or during at least one Trastuzumab-con
Inclusion completed
SE
Breast cancer
A Phase II, Randomised, Double-blind, Placebo-controlled, Multi-centre Study to Assess the Efficacy and Safety of AZD8931 In Combination with Anastrozole, Compared to An-astrozole alone, in Post menopausal Women With Hormone Receptor positive, Endocrine T
Open for inclusion
FI
Breast cancer
A prospective phase II study to evaluate alternations in molecular biomarkers in HER2-positive metastatic breast cancer together with assessment of trastuzumab use beyond progression efter initial exposure to trastuzumab-taxane based treatment
Open for inclusion
SE
Breast cancer
First in human study in HER2 positive primary breast cancer patien
eligible for neoadjuvant chemotherapy
Open for inclusion
DK
Breast cancer
Intra-hepatic chemotherapy in
from breast cancer patie
extrahepatic disease are included
Open for inclusion
DK
Breast ca
breast cancer and limited extrahepatic disease
Open for inclusion
DK
Breast cancer
Pre-Operative Study of PF-4691502 With Letrozole Compared To Letrozole Alone In Patients With Early Breast Cancer
Open for inclusion
SE
Breast cancer
Randomized phase II study of afatinib alone or in combination with vinorelbine versus investigator's choice of treatment in patients with HER2-positive breast cancer with pro-gressive brain metastases after trastuzumab or lapatinib based therapy
Open for inclusion
FI
Cholangiocarcinoma
A phase II trial evaluating intra-hepatic chemotherapy with oxaliplatin every second week in combination with systemic gemcitabine and capecitabine in combination with cetuximab in patient with non-resectable liver metastases from cholangiocarcinoma
Open for inclusion
DK
Colorectal cancer
Assessmant of safety and immunogenicity of intradermal electroporation of tetwtCEA DNA in patients with colorectal cancer
Inclusion completed
SE
Colorectal cancer
Intra-hepatic and systemic chemotherapy with or without antibody for patients with non-resectable liver metastasis from solid tumours
Open for inclusion
DK
Colorectal cancer
Open-label , single-arm, phase II study of bevacizumab (Avastin) in combination with alternating Xeliri and Xelox as first-line treatment of patients with metastatic colorectal cancer
Open for inclusion
FI
Randomized Double blind Placebo Controlled Gross-over Phase II study on the effects of Lactobacillus Rhamnosus GC supplementation in patients on 1st
Inclusion
90 trials registered, Oct 24th, 2017







Visit the Nordic NECT web pages at:
*www.nordicnect.org*

## Challenges for Cross border patients

- All patients have access to urgent medical services
  - EU inhabitants are charged by their home countries
  - Other patients pay by themselves or an insurance
- EU patients have full access to non-emergency medical services by E112/S2 form
  - Treated disrespected of their nationality
- EU directive allows patients to choose another EU country for health care services
  - –requires a permit prior to transfer

**REAL CHALLENGE: Does not cover clinical trials!**



## Are all countries equal?

- Poor survival rates in Denmark compared to the Nordic pushed for improvement -> allow treatment abroad
- Politicians past a bill to allow patients the right to seek highly speciliazed and experimental treatment abroad
- EU directive already exists
- Pts with tumours that harbour rare driver mutations should be referred to institutions offering relevant trials with targeted therapy
- Requires a recommendation both from the treating physician and institution. Patients can also seek trial treatment in Denmark if the referring institution has issued the E112/S2. Norway has also decided to establish an expert panel whom can send patients abroad for trial treatment.

## Real life..?

- 79 year old norwegian male diagnosed with bladder cancer in 10/2013, lymph node metastasis in 10/2015 and systemic treatment initiated according to standard practice.
- Response initially until 01/2017 progression
- No uniform standard treatment for 2nd line exists until 05/2017 when nivolumab (PD-1 inhibitor) approved by EMA. Hospital approval granted in Helsinki as of 09/2017. Approval still lacking in many hospitals including the patient's referring institution.
- Referred to Helsinki by the treating physician for a phase II trial investigating the combination of nivolumab and ipilimumab in 06/17.
- After 4 cycles -56% reduction in tumour burden. Patient is in excellent condition experiences only minor side effects.

- Challenge: Treatment and expenses on land covered by the trial but airline costs by the patient



## Expanding borders even further…