



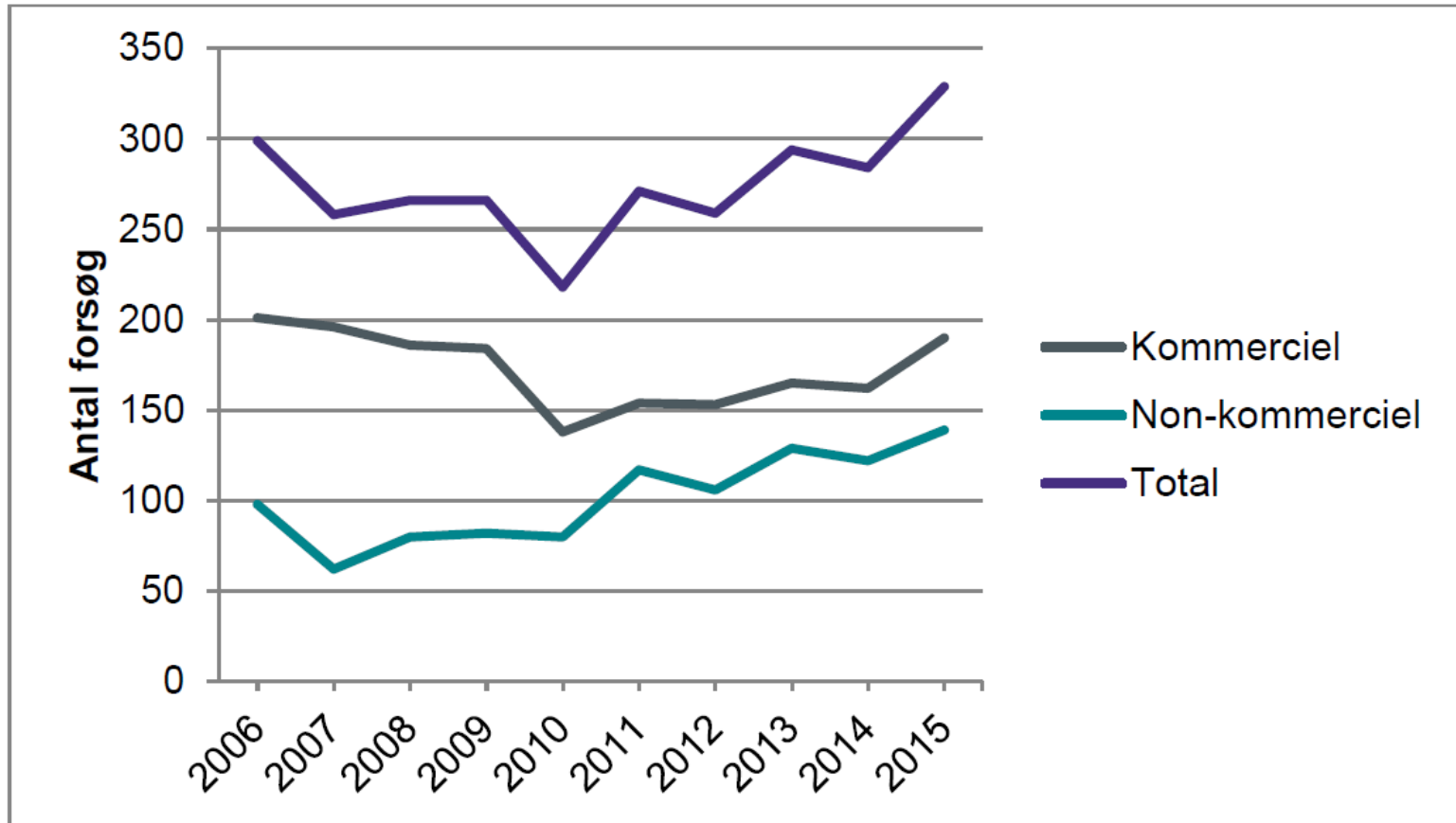
next  
NATIONAL EXPERIMENTAL  
THERAPY PARTNERSHIP

# National Experimental Therapy Partnership

Britta Smedegaard Andersen



# Clinical Trials Initiated in Denmark, 2006-2015



# To Turn The Curve



# NEXT is a Contribution to the Danish Government's Innovation Strategy

- Politically priority to make Denmark a country where innovative solutions to Danish and global challenges are converted into growth and employment by establishing societal partnerships
- NEXT is a public-private partnership funded by Innovation Fund Denmark
- NEXT was established in 2014 and will in 5 years make *Denmark a country of choice for early clinical research*
- By establishing centres for experimental research and "*Proof of Concept*" trials
- Based on organisational innovation

# Formation of NEXT – Key Do's

- Lobby from the Danish Pharmaceutical Industry Association “Lif” to the Innovation Strategy of the Danish Government
- Joint application between the Danish regions and the pharmaceutical industry with one strong operational chair and a strong “NEXT application board”
- A national approach to ensure all regions are interested
- Industry commitment in early phase trials in specific disease areas
- Regional commitment of co-financing of staff manpower

# NEXT – A Unique Public Private Partnership

- **Denmark as a country of choice for early clinical trials of new drugs in patients**
  - Based on a close collaboration across hospitals ensuring **national recruitment of patients**
  - Involving research activities in universities and hospitals within **precision medicine**
- **NEXT experiences a fast start with remarkable interest from industry and hospitals**
- **Partnership combined with huge political interest and support from government**
- **Oncology & haematology & bioinformatics  
Dermatology, Respiratory Medicine &  
Infectious Diseases**



# What does Denmark gain from NEXT?

## **Patients:**

Access to new medical treatment and possibility of personalised patient treatment, involvement in drug development processes

## **Industry:**

Easy access to excellent research environments in Denmark, fast clinical trials, access to unique health data, closer public-private collaboration

## **Precision medicine**

## **Healthcare System:**

Experiences with new medical treatments, education of staff, increased possibilities for patient treatment, income

# If Industry is to place early clinical trials in Denmark

## Quality

- Clinical quality & standard processes
- Predictability in clinical trials
- Structured set-up of clinical units

## Access

- A national mindset with:
- One entrance – disease specific
- One entrance other relevant areas

## Visibility

- Marketing of NEXT centres & NEXT Link in DK and abroad
- Partnership in NEXT

# Key Improvements in Public-Private Collaborations with NEXT

- Quality criteria to be a NEXT hospital department
- Increased visibility of the excellent clinical trial units in NEXT
- Optimised national feasibility and clinical trial set-up
- Site oversight of trial performance & a proactive / innovative approach
- Improved patient recruitment in a national setting (referrals & patient databases)
- One master template national CDA
- One master template CTA
- Centralised budget negotiations
- Increased visibility of private partner companies
- Marketing activities for Danish Clinical Trials with NEXT
  - Locally in Denmark
  - Internationally in collaboration with Ministry of Foreign Affairs / Invest in Denmark

# NEXT Partners

Founding Partners

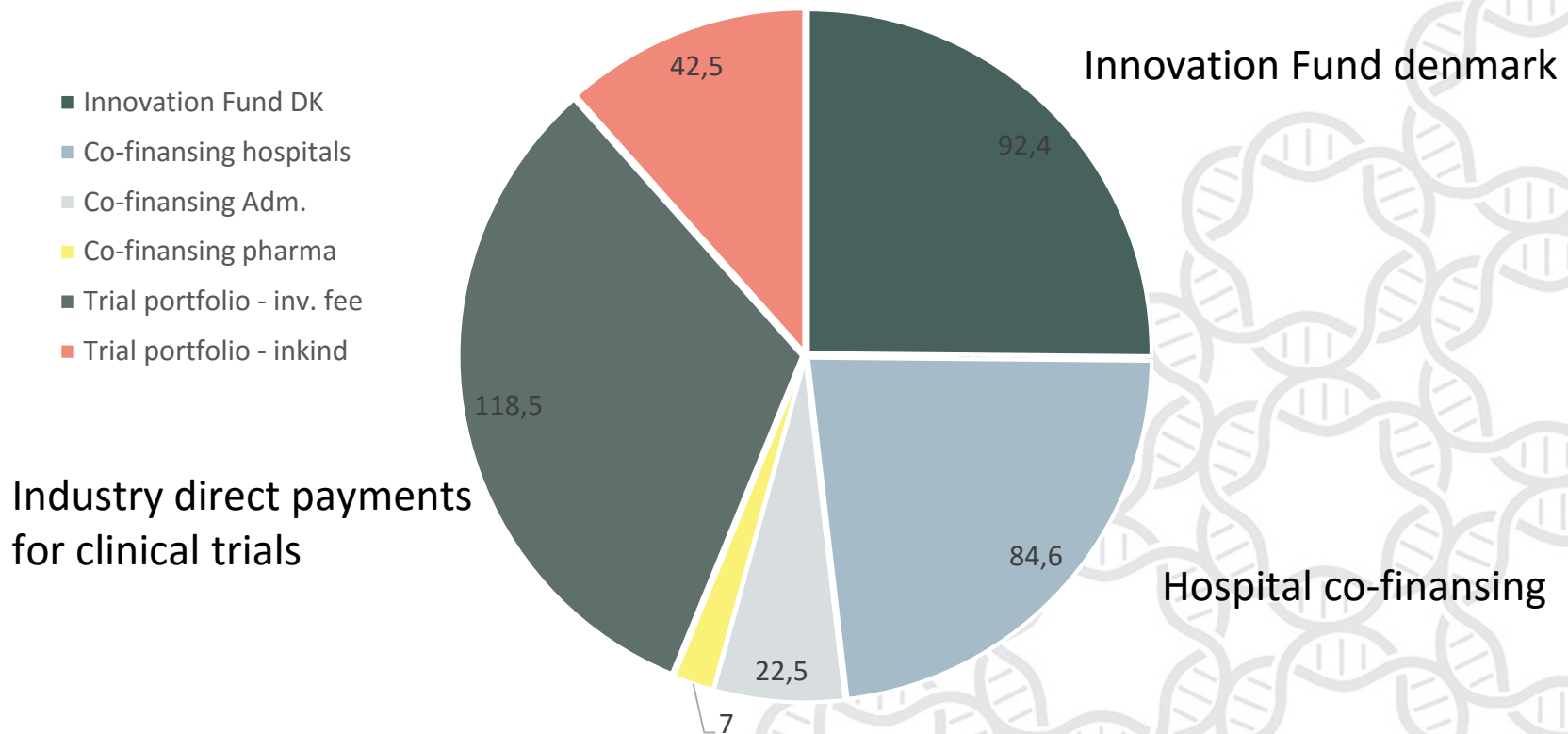
Partners

Associated Partners



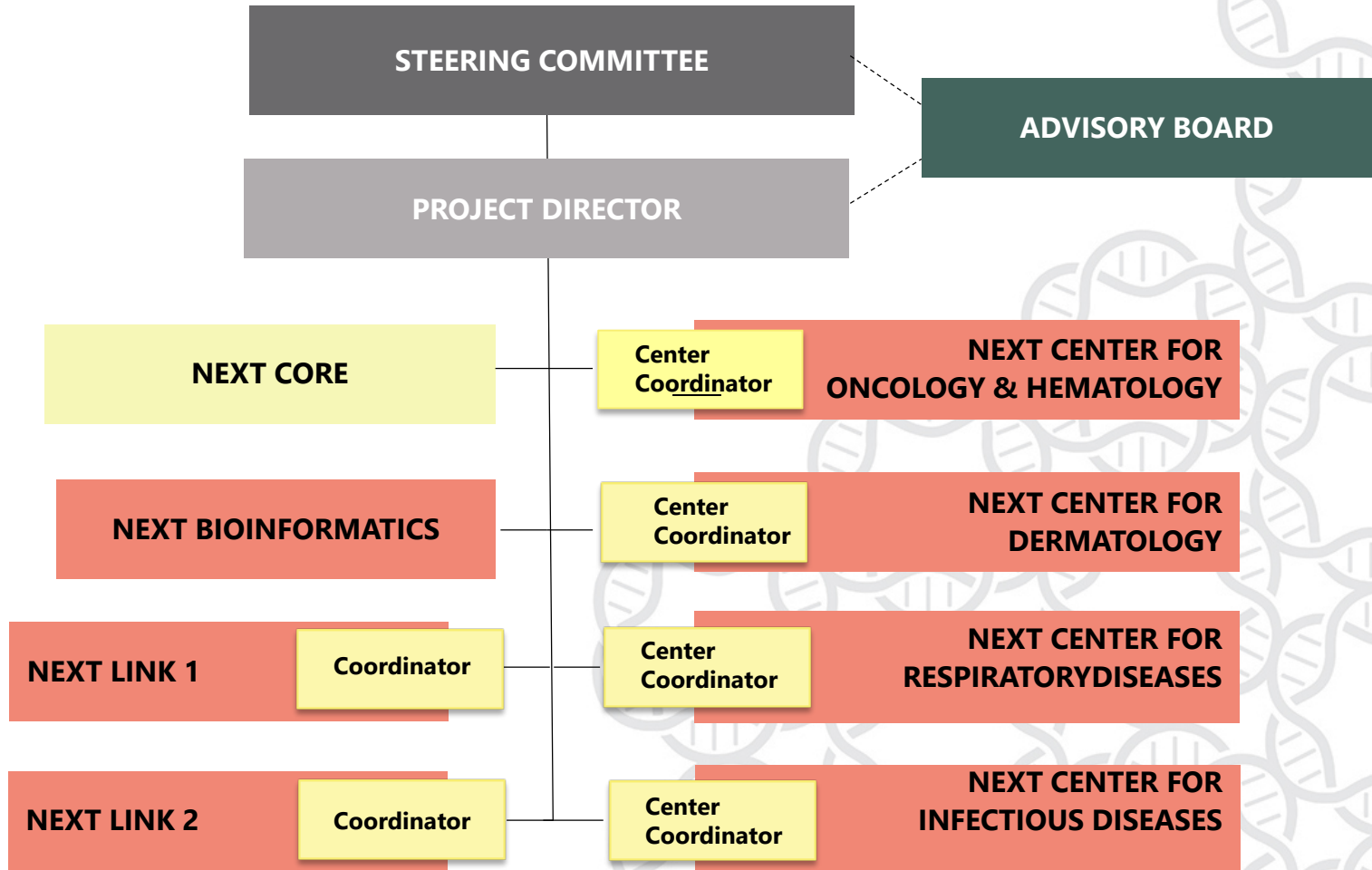
# NEXT Budget

Total budget = 368 mio. DKK



Industry direct payments  
for clinical trials

# NEXT Organisation



# NEXT Steering Committee



**Ulrik Tarp**  
Næstformand  
Region Midt



**Thomas Kongstad Petersen**  
Formand  
LEO Pharma



**Rosa Andersen**  
Næstformand  
Region Hovedstaden



**Poul Andersson**  
Bioneer A/S



**Dorte Klokker**  
Roche



**Karin Kramer Nielsen**  
Novo Nordisk



**Søren Hjortshøj**  
Region Nord



**Charlotte Aagaard**  
MSD



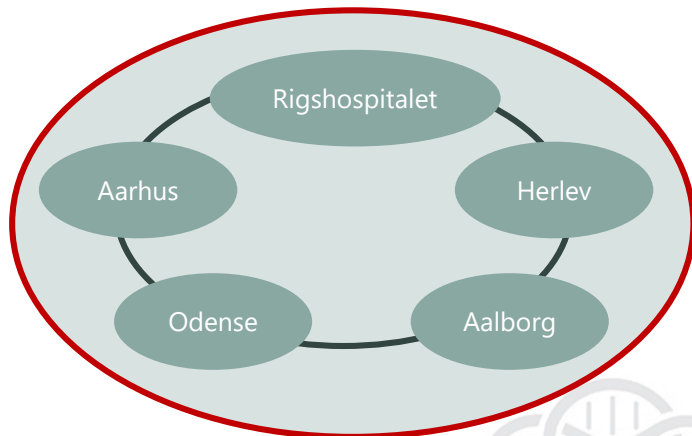
**Mahad Mussa Huniche**  
Region Sjælland



**Kim Brixen**  
Region Syd

2

Center for Oncology & Haematology evaluates the request in the Coordination Group



1

Request for feasibility for an early clinical study in Denmark is send to the Center Coordinator at Rigshospitalet

3

Compiled response to requester is sent from Center Coordinator: fast high quality excecution of clinical study in Denmark

Requester

The requester evaluates the response

4

# The NEXT Team



Camilla Hauge  
Respiratory Medicine



Ask Aabenhus  
Oncology & Haematology



Karina Markersen  
Dermatology



Jørn Falch  
Infectious Diseases

# NEXT will Expand

**Associated partners**

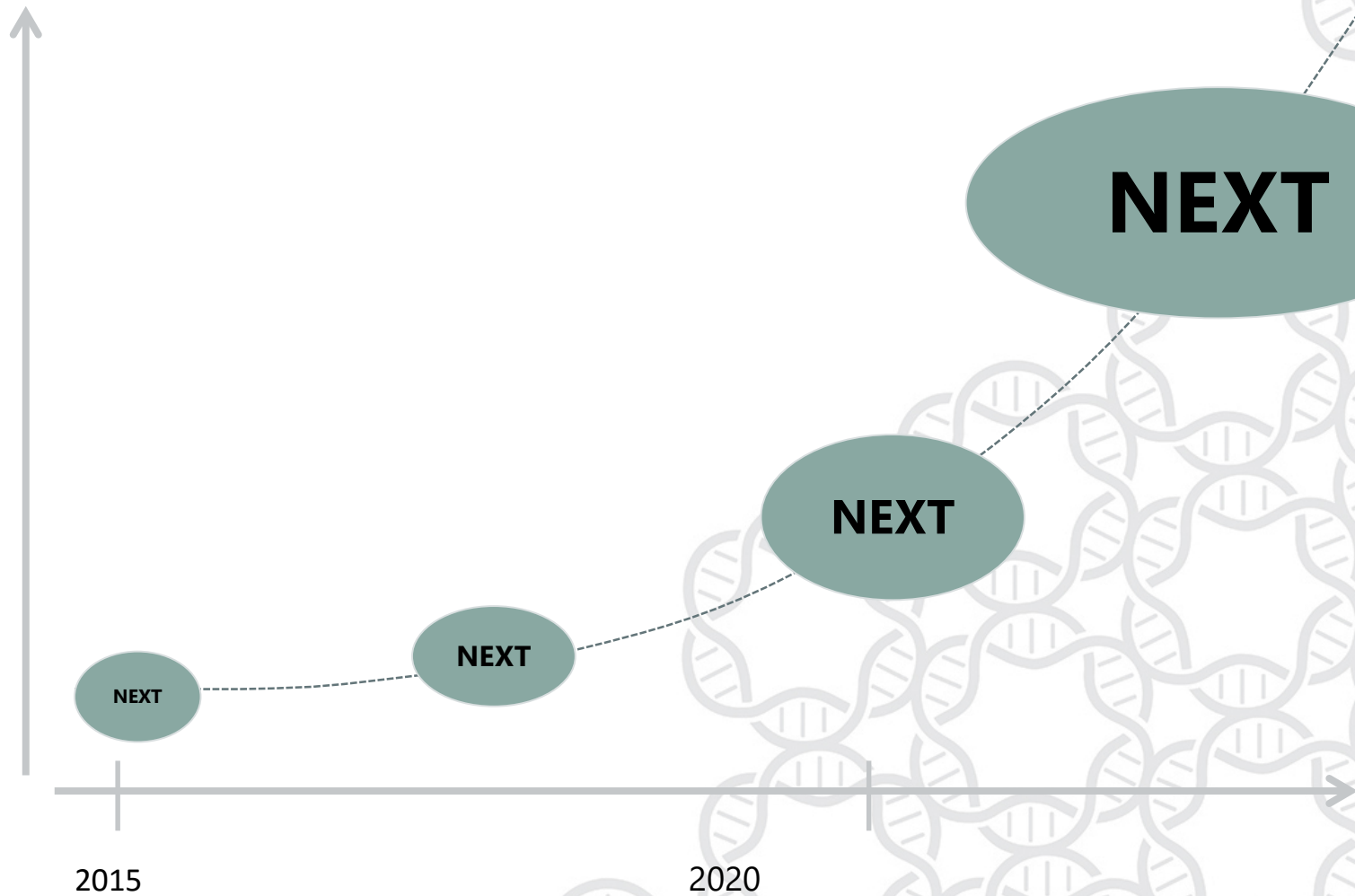
**Establishment of  
research networks  
– NEXT Link**

**Associated hospital  
departments**

# The Way Ahead

- NEXT must be self-financed from 2020
  - This is a stipulation of the Innovation Fund from the time of the investment
  - The NEXT Core function must continue
  - Incentives for clinical research must be clear in the healthcare system
  - Keep the partnership idea in the set-up
- NEXT will cover all major disease areas and all clinical phases of drug and medical device development

# NEXT is just the start...



# Challenges

- Clinical readiness to start clinical trials fast – staff time / resources
- Incentives in the hospitals for doctors and nurses to engage in commercial clinical trials
- Hospital acknowledgement of local clinical trial units performance in commercial clinical trials
- Local Authority & Ethics Committee approval time
- Administrative hurdles in the hospitals eg. time spent with legal negotiations of clinical trial contracts

# Key Learnings – governance & model

- Partnership as a model is unique
- Preferably the board consists of public representatives and private representatives and chairman is private
- A neutral Project Director
- A neutral co-ordinating facility to ensure a national approach in the set-up
- Hospital in-kind is a challenge – staffing is to be prioritised

# For more information:

**WWW. nextpartnership.dk, E: bsa@nextpartnership.dk, M: +45 30 45 97 68**

## ABOUT NEXT

NEXT - National Experimental Therapy partnership - is a public-private partnership within clinical research which comprises six public institutions and five pharmaceutical companies. The partnership was established on 1 November 2014 as an Inno+ partnership, with Innovation Fund Denmark (Innovationsfonden) investing DKK 50 million in the partnership over a five-year period, and the partners investing DKK 74 million.

NEXT will establish Denmark as a country of choice for the pharmaceutical industry for carrying out early clinical trials of new drugs on patients. In particular, NEXT will focus on proof of concept trials.

NEXT is working to optimise all processes relating to the start-up and implementation of clinical trials, where optimising legal and statutory processes has a high priority. A high degree of predictability in the clinical trials is also a key element of NEXT. The trials are being started as planned, and the agreed number of patients are being recruited.

[READ MORE](#)

# Clinical Trial Services in Denmark

Client with a  
clinical trial  
request

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Respiratory medicine  
Oncology and haematology  
Infectious diseases  
Dermatology

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Paediatric diseases

**Paediatric Research Network,  
DanPedMed**  
Marie Louise S. Nilsson  
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All other areas of diseases

**Clinical Trials Office Denmark**  
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+45 29 17 08 72

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# Clinical Trial Services in Denmark

Client with a  
clinical trial  
request

 **Clinical Trials Office**  
**Denmark**



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NATIONAL EXPERIMENTAL  
THERAPY PARTNERSHIP

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[www.nextpartnership.dk](http://www.nextpartnership.dk)  
[info@nextpartnership.dk](mailto:info@nextpartnership.dk)

# Back-up



# Key Characteristics for Successful Performance in Clinical Trials Industry Needs



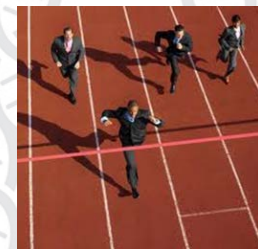
**Focus on performance in clinical trials ●**

**● Flexibility in the hospital system**

**Fast start up of clinical trials ●**

**● Committed investigators & nurses**

**Easy access to investigators ●**



# Industry: A National Approach is needed in the Global Competition – even Nordic?



## Three political levels

Government

Five regions:

Capital Region of Denmark

Region Zealand

Region Southern Denmark

Central Denmark Region

North Denmark Region

98 municipalities

# Key Characteristics for Successful Performance in Clinical Trials

## Investigators need



Staff support resources especially in the start-up process of clinical trials, Clinical Trial Units

Jobs combining research and care

Incentives to engage in clinical trials

Dedicated time to perform clinical trials

Training & education, eg. GCP

