

HANDLINGSPLAN FOR STYRKEDE RAMMER FOR OFFENTLIGT-PRIVAT SAMARBEJDE OM KLINISK FORSKNING

UDARBEJDET AF MINISTERIET FOR SUNDHED OG
FOREBYGGELSE, UDDANNELSES- OG FORSK-
NINGSMINISTERIET OG DANSKE REGIONER

MAJ 2014

**DANSKE
REGIONER**




**MINISTERIET
FOR SUNDHED
OG FOREBYGGELSE**



**Uddannelses- og
Forskningsministeriet**

2.2 Summary

Background

This action plan is an initiative from the Danish' Government's growth plan regarding health and welfare solutions.

Denmark has a long tradition of cooperation between public and private parties in clinical research. Clinical research is considered a prerequisite for an ongoing development of health services and for better and more effective treatments for patients. Clinical research is one of Denmark's absolute strengths and much of it is completed in cooperation between public and private parties. However, it is a position of strength under pressure.

Purpose of the action plan

The purpose of the action plan is to strengthen the framework for cooperation in clinical research between the public health sector and the private industry. The overall objective of the future is that Denmark attracts more clinical research which is carried out in cooperation between public and private parties. It is expected that more and better clinical trials of both medicinal products and medical equipment will contribute to better treatments and consistency in Danish health services while strengthening Danish knowledge, research, and growth.

The action plan outlines a number of concrete objectives and the action plan contributes to their realization.

The objectives of the action plan

The implementation of the action plan's 10 initiatives is to lead to the following objectives:

- The number of clinical medicine trials by public – private cooperation is increased by 10 percent over a period of 3 years (both private and public initiated trials).
- 20-30 more private initiated trials (both medical products and medico equipment) are based in Denmark over a period of 3 years.
- The number of clinical tests of medico equipment by public-private cooperation is increased by 5 pct. over a period of 3 years.
- The number of test subjects in clinical research by public-private cooperation is increased by 5 pct. over a period of 3 years.
- The effort to secure high quality in clinical research conducted by public-private cooperation persists during the next 3 years.

Why public-private cooperation in clinical research?

Clinical research is by nature closely linked to the everyday practice in health care. Much of the clinical research is conducted as a fully integrated part of everyday life in health care. The strengthening of public -private cooperation in clinical research will generate new knowledge. New knowledge will benefit both patients and the private industry. Strengthening the cooperation between public and private parties in clinical research must be done in respect of the conditions and needs of patient safety transparency, quality and efficiency that comprises both parties.

Focus

The action plan includes concrete initiatives to improve the framework for both public and private parties involved in the cooperation in clinical research. This means that the implementation of the initiatives in the plan of action requires an effort from both public and private parties.

The action plan focuses on two dimensions of cooperation:

- Management, planning and regulation: Making the cooperation possible and transparent.
- Collaboration and dialogue: Making the cooperation attractive and efficient.

Summary of Initiatives

The action plan includes 10 concrete initiatives to improve the framework for both public and private parties involved in the cooperation in clinical research. The following initiatives provide an overview of the action plan's two focus areas, their overall purpose, their objective, and finally the specific initiatives.

Additionally, the action plan's initiatives will be monitored regularly. The National Cooperative Forum of Health Research contributes to the regularly monitoring of the initiatives' implementation.

Focus area 1: Management, planning og regulation: Make the cooperation possible and transparent

Purpose – why a plan of action?

In order to strengthen the framework for public - private cooperation in clinical research, it is necessary to focus on how to prioritize research opportunities through planning, management, and clear rules.

It will become easier for scientists to carry out research while management at various levels should clarify the feasibility and priority of public-private cooperation in clinical research.

The expectation is that a management focus, time in everyday life and a clear and transparent framework will support a positive culture of healthcare employees in order for public - private cooperation in clinical research to be perceived as legitimate.

Initiatives – What does it take?

- Initiative 1: Encourage the establishment of combined education positions (kombinationsuddannelsesstilling).
- Initiative 2: Encourage the establishment of divided positions (delestilling).
- Initiative 3: Support the procurement rules for healthcare personnel cooperation with the medico and medicinal industries.

Objective – What will we achieve and how do we measure it?

The objective is that:

- The possibility of combination education positions is enhanced over a period of 3 years through increased flexibility and management focus subsequently.
- The possibility of divided positions is enhanced over a period of 3 years through increased flexibility and management focus subsequently.

In addition, the objective is that the research area before 2017:

- Has an independent role in the management structure and therefore becomes a visible part of the management in the hospitals and regions.
- Is integrated into everyday clinical practice.
- Has a budget financing research in all hospitals and in all regions.
- Is more transparent in relation to the management of accounts at hospitals so that each region has a system to ensure accountability and transparency in relation to research funds.
- Supports the practice sector. This includes creating a model that makes the GPs a part of a research cooperation with the private industry.

Focus area 2: Collaboration and dialogue: make the cooperation attractive and efficient

Purpose – why a plan of action?

In order to strengthen the framework for public-private cooperation in clinical research it is necessary to focus on how it is made attractive and manageable to engage in such cooperation. It must be possible for the private industry to get in contact with relevant research networks. The relevant authorities must provide a prompt processing of high quality and the possibility to recruit a sufficient number of patients.

Initiatives – What does it take?

- Initiative 4: Strengthening of national cooperation and patient recruitment including the establishment of national research networks under the auspices of *One Point of Contact*.
- Initiative 5: The establishment of a Social Partnership concerning Denmark as the favored country to carry out early clinical trials of new medicine (INNO+).
- Initiative 6: Relevant authorities and industry must make the good framework for clinical research in Denmark visible.
- Initiative 7: Strengthening the clinical research and the public-private cooperation in the GPs.
- Initiative 8: Possible initiative from the authorities (fast track, guidance and authorization procedure).
- Initiative 9: Focus on the medico industry in *One point of Contact*.
- Initiative 10: The possibilities of research in municipalities.

Objective – What will we achieve and how do we measure it?

The objective is that:

- Five new and national research networks are established over a period of 3 years.
- The number of clinical medicine trials by public – private cooperation is increased by 10 pct. over a period of 3 years.
- The number of clinical tests of medico equipment by public-private cooperation is increased by 5 pct. over a period of 3 years.
- The number of GPs in research networks is increased over a period of 3 years.
- The relevant authorities scrutinize possible and future initiatives of the authorities concerning clinical trials in 2014.
- Medico becomes an integrated part of *One point of Contact*.
- It becomes clear and transparent how public and private employees cooperate.
- The municipalities focus on the clinical research and participating in clinical research projects including public-private research projects.