



MINISTRY  
OF HEALTH



DANISH  
REGIONS

# PERSONALISED MEDICINE FOR THE BENEFIT OF PATIENTS

CLEAR DIAGNOSIS  
TARGETED TREATMENT  
STRENGTHENED RESEARCH

**SUMMARY** · NATIONAL STRATEGY FOR  
PERSONALISED MEDICINE 2017-2020





# Personalised Medicine for the benefit of patients

## The Danish healthcare system has unique possibilities of realising the potential of Personalised Medicine.

For many years, the Danish healthcare system has systematically collected data and knowledge about the Danish population's diseases and treatment. It has helped us better understand which treatments that work, and which that do not work.

It is through the research we conduct with the many that we can make a difference for the individual.

### **We owe it to the patients to use this position of strength.**

The Danish people expect a healthcare system that offers them the best possible treatment.

Even though we have come far, there are still many diseases that we do not know enough about. It makes it a challenge to diagnose and treat patients appropriately and quickly.

We have to recognize that not all medicines work for every patient. Arthritis or cancer patients, for example, sometimes have to try out a number of different treatments and may experience a multitude of side effects along the way. There are also diseases whose cause we cannot explain, which makes it difficult to find the appropriate treatment.

It does not have to be this way in the future.

With Personalised Medicine we can develop new treatments through the use of knowledge and new technologies. By using genetic knowledge about the disease and the individual patient, we can diagnose diseases more precisely and target treatment more accurately.

The advances are happening right now, especially on the international scene. In Denmark, the healthcare system and research environment are working to gain new knowledge and achieve better results for patients. But the activities lack coordination, and we wish to build a stronger collaboration.

If the Danish people are to benefit fully from new technologies and other advances, we must collaborate across the nation – both in the healthcare system and the research environment. Diagnosis, treatment, research, infrastructure, ethics and safety must be developed hand in hand.



It is a long haul, but it is important for the Danish patients.

We still have a lot to learn about our genes. The new possibilities also raise new clinical, legal and ethical questions. We must address these questions, and we need to be thorough and do it wisely.

With the National Strategy we lay the tracks for the continued development of Personalised Medicine in Denmark. The Government and Danish Regions agree that the new possibilities must benefit the Danish people.

We share this wish with patient organisations, universities, organisations, the Danish research environment and the many professionals who have contributed to the foundation of this strategy. Together we build the new elements on the solid basis that already exists in Denmark.

Ellen Trane Nørby  
Minister for Health

Bent Hansen  
President, Danish Regions

# Status in Denmark



**The advances are happening right now in Denmark – both within the research environment and the healthcare system.**

For a long time, we have used genetic information in the field of hereditary diseases. But the underlying techniques are now increasingly being used in other areas, e.g. in cancer treatment and pre-birth diagnosis.

Many hospital departments use or are planning to use genome sequencing techniques. A majority of medical specialties expect to start using genome sequencing in the nearest future.

It is therefore crucial to the future work with Personalised Medicine in Denmark that relevant clinical activities and underlying infrastructures are consolidated and streamlined.

Many universities and hospitals are conducting research in the area, and research takes place in all stages of the value chain – from basic genome research to research in clinical practice. Research on ethical and societal aspects is conducted as well.

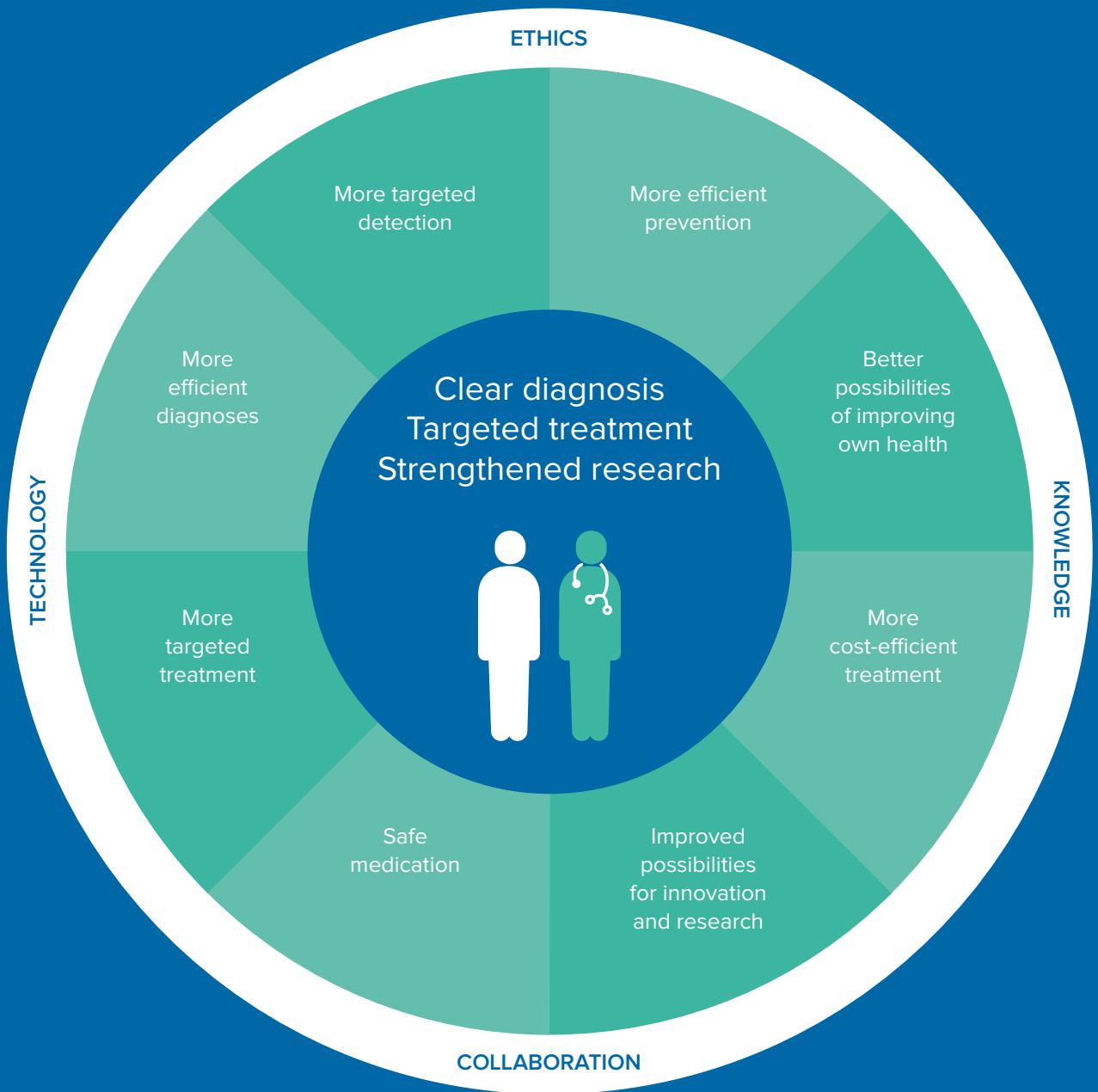


It is estimated that more than DKK 500 million have been invested in research infrastructure of relevance to Personalised Medicine in recent years. Funds have been channelled to biobanks, genome sequencing equipment and supercomputers capable of processing large volumes of genetic information to gain new knowledge about the role of genes.

Personalised Medicine is making fast progress overall. If Denmark is to be at the forefront of development, and the Danish people are to benefit from new technology, it calls for collaboration and coordination of the increased activities.

The use of data will grow along with the rapid development. It is about realising the potential by linking what we already know about the population's diseases with genetic knowledge.

Researchers must have secure, quick and easy access to pseudonymised data so that new knowledge and new treatment forms can be developed to the benefit of patients. Data and knowledge are to be shared in a secure manner for doctors to be able to diagnose more precisely and target treatment more quickly than the case is today.



# Principles and action areas of Personalised Medicine in Denmark

With this strategy, we lay the tracks for the use of Personalised Medicine in the Danish healthcare system – and for the research that is to realise the potential of Personalised Medicine. We lay the tracks for progress that is to evolve into the future.

We have formulated six principles that will underpin this development as we acknowledge the importance of being open about the underlying considerations associated with Danish efforts in the area of Personalised Medicine.

The Government and Danish Regions agree on the six principles that are intended to guide the work with Personalised Medicine. The principles are to ensure that we work within the same framework.

We still have much to learn about the link between genetics and development of disease. Therefore, the primary target group of genome sequencing is not healthy people. It is important that the realisation of the strategy does not give rise to needless insecurity, overdiagnoses and waste of resources.

## The strategy's six principles

- 1 The Danish efforts within Personalised Medicine are to focus on the patients. Genome sequencing is to be used for treatment purposes and in research projects.
- 2 Confidentiality, the individual's right to self-determination, protection of information and research ethics approval are paramount.
- 3 The use of Personalised Medicine as a standard offer in the healthcare system must be evidence-based and economically sustainable.
- 4 Genome sequencing and data processing must be based in the public sector.
- 5 The national infrastructure and adopted standards must be used, and data must be shared securely for the benefit of future research and treatment.
- 6 The distribution of research funds as part of the strategy must take place in competition – and research projects should in principle be nationwide.



### National strategy – action areas at a glance

The development and implementation of Personalised Medicine in the healthcare system require that many initiatives are initiated and evolve in parallel. Many areas have to come together. The Government and Danish Regions have therefore agreed on seven strategic action areas. Together, they will guide the work in the coming years.



The work with the strategic action areas should be based on and consolidate the structures and efforts already in place within the healthcare, research and education, etc.

# Strategic action areas



## **TRANSPARENT GOVERNANCE STRUCTURE WITH NATIONWIDE INVOLVEMENT**

The work must be nationwide and open. The national coordination is to ensure balanced advances in the area of Personalised Medicine, taking into account relevant concerns and facilitating the decentralised implementation in the healthcare system. A key concern in this respect is to ensure an appropriate balance between central control and locally embedded action areas.



## **CLEAR LEGAL FRAMEWORK ADDRESSING ETHICAL PRINCIPLES AND DATA PRIVACY AND SECURITY**

It is essential to ensure appropriate protection of the rights, health, integrity and self-determination of research participants and patients while ensuring that advances in the healthcare system are made for the benefit of patients. Thus, it is essential for the trust in the Danish development of Personalised Medicine that the action areas rest on comprehensive information efforts as well as on a solid ethical, legal and data safety-related basis. We must ensure the continuous development of knowledge about the ethical, legal and societal aspects that are associated with the implementation of genome sequencing and Personalised Medicine in the healthcare system.



## **PATIENTS AND CITIZENS MUST BE INVOLVED**

The development of Personalised Medicine will depend on Danish patients' and citizens' information about treatment and research. Openness and dialogue with the public are therefore imperative. The involvement of patients and the public is required, and information sharing, communication and involvement will be central action points.



## **A TECHNOLOGICAL INFRASTRUCTURE WITH SECURE, EFFICIENT AND EQUAL ACCESS**

The collaboration on Personalised Medicine will increase the need for a joint infrastructure to collect and store biological samples and data, conduct genome sequencing and for registration, processing and sharing of data. The nationwide infrastructure must accommodate both treatment and research of significant public importance. It must also exploit and interact with the existing central and local infrastructures already in place in the healthcare system and research environment.



## **GENOMICS RESEARCH MUST BE INTERNATIONAL AND DEEPLY INTEGRATED IN THE HEALTHCARE SYSTEM**

Treatment, research and development go hand in hand. It is through the research we conduct with the many that we can make a difference for the individual. There must be a clear and secure framework for cooperation between clinical practice and research, including for the use of data, nationally and internationally. Research and development must be based on clinical challenges, relevant patient and risk groups and disease areas. The costs and effects of projects within the strategy must be evaluated to gain knowledge about cost-effectiveness.



## **TOOLS AND COMPETENCIES TO USE GENETIC DATA**

It is important that future clinical practice is based on solid evidence. A knowledge base and a permanent, professional collaboration must be set up to work with the meaning of genetic differences for use in everyday clinical practice. Relevant healthcare professionals must be capable of using genetic information and informing patients and relatives about the contents and meaning of patient treatment. It is also important for the development of the area that we have adequate, professional resources and mobility among staff.



## **DENMARK MUST HAVE AN ATTRACTIVE DEVELOPMENT ENVIRONMENT IN RELATION TO PERSONALISED MEDICINE**

Denmark must be at the forefront. The area of Personalised Medicine has the potential of becoming an important Danish research area. There are promising possibilities within public-private collaboration on new treatment forms – e.g. new medicines – that will benefit patients.

The governance structure is to ensure a clear framework for collaboration between public researchers, clinicians, patients and private companies. The governance structure is a prerequisite for strong and secure collaboration throughout the research value chain. Data can only be used as part of treatment in the healthcare system or for statistical and scientific work of significant public importance.

# The focus of the strategy – and the way forward

The realisation of the strategy and the seven action areas call for dedicated efforts for many years to come.

The Government and Danish Regions agree that a Danish strategy for Personalised Medicine in the healthcare system through the use of genetic information is to focus on patient needs as well as clinical needs. The focus should be on diseases and risk groups as a basis for research and development.

In the short term (2017-2020), the Government and Danish Regions will collaborate on the realisation of the strategy in phases.

The first phase is initiated in the beginning of 2017. The establishment of the needed infrastructure will form the basis for research projects that may also start in 2017 and which, depending on the funding possibilities, may be upscaled over subsequent years.

## PHASE 1

### **Establishment of joint governance**

- Formation of a board with up to 15 members
- Establishment of a research committee
- Establishment of an ethics committee
- Establishment of a patient and citizen advisory group
- Continuation of the reference group
- Establishment of an international advisory board
- Regional consolidation and harmonisation of existing clinical activities, support functions, etc.
- Education and competence development for employees in the healthcare system and research environments

### **Establishment of a national genome centre**

- Establishment of collaboration on a secure, joint and nationwide technological infrastructure to enable genome sequencing and expansion of the storage of data
- Establishment of registration, processing and sharing of data in a national genome database
- Establishment of collaboration on secure, flexible and equal access for researchers and clinicians to use genotypic and phenotypic data for treatment and research purposes within the legal framework
- Information for patients and citizens
- Establishment of a national base and collaboration on knowledge sharing for clinical practice and clinical ethics



## PHASE 2

### Research and development

- Consolidation of relevant regional research support within Personalised Medicine
- Initiation of relevant research projects within Personalised Medicine, including also ethical and societal relevant research
- Continuous focus on ethical and legal aspects

The areas of genomics research and Personalised Medicine are constantly evolving, and therefore, it may become relevant to review the strategy or consider new action areas along the way. Furthermore, a review of the legal framework for use of biological material and data derived from biological material has already been initiated.

There is considerable potential for using genetic information for diagnosis, treatment and prevention in many areas of disease. The Government and Danish Regions agree that the Danish efforts within Personalised Medicine should focus on research and genome sequencing within disease areas and risk groups. In the long term, it may be relevant to expand our efforts with other technologies.

**Generally, the focus should be on disease areas and risk groups characterised by the following:**

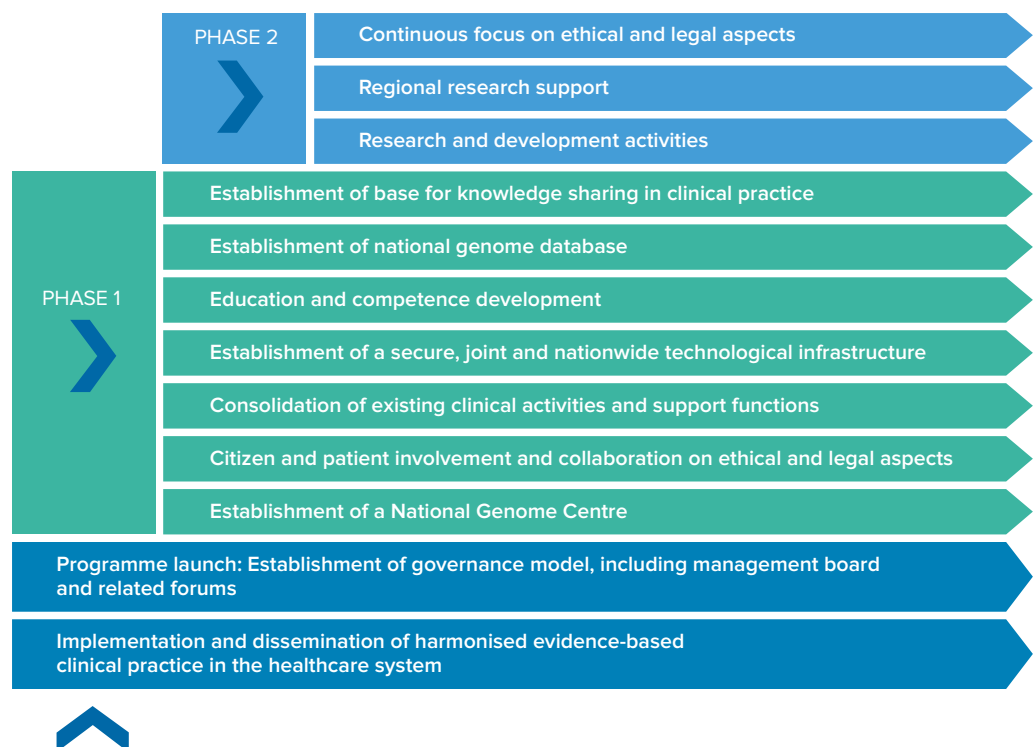
- Those posing special challenges to the Danish society, e.g. affecting a lot of patients or relatives
- Those associated with a significant genetic component, also having a considerable research potential
- Those in which progress and new results are anticipated in the short term, e.g. in the form of better or new treatment forms

Research projects within the strategy must have an adequate volume and must generally be nationwide.

Areas in which Denmark is expected to deliver high-quality research should also be in focus. For example, potentials are anticipated in research and genome sequencing within a number of fields, e.g. cancer and major preventable diseases and disorders, neurological diseases/psychiatry, infections and autoimmune disorders and rare diseases.

All relevant research projects and clinical activities, whether or not within the strategy, must be able to use the organisational and technological infrastructure. Thus, the infrastructure is intended to accommodate clinicians and researchers in general, and may also be used for projects funded outside the scope of this strategy. Moreover, the intention is for the total infrastructure to serve as a common national resource and research infrastructure, providing access to research on equal terms.

Illustration of the implementation of the strategy's elements





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