



DANISH MINISTRY  
OF HEALTH



DANISH  
REGIONS

# PERSONALISED MEDICINE FOR THE BENEFIT OF THE PATIENTS

CLEAR DIAGNOSIS  
TARGETED TREATMENT  
ENHANCED RESEARCH

NATIONAL STRATEGY FOR  
PERSONALISED MEDICINE 2021-2022



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# Personalised medicine for the benefit of the patients

The Danish healthcare system has unique possibilities for realising the potential of personalised medicine.

For many years, the Danish healthcare system has systematically collected data and knowledge about the diseases and treatment of the Danish population. This has provided us with more knowledge of treatments that work and treatments that do not.

The Danish health data holds a unique opportunity to strengthen research and development within personalised medicine. Through research into many people, we can make a difference for the individual.

## **We owe it to the patients to take advantage of this position of strength**

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

Even though we have come a long way, there are still many diseases that we do not understand well enough. When it comes to correct and timely diagnosis and treatment of patients, this is a challenge.

At the same time, we have to acknowledge that not all medicines are effective for every patient. Sometimes, arthritis or cancer patients have to try out a number of different treatments or may experience a multitude of side effects. There are also diseases with no known cause. This makes it difficult to find an effective treatment.

However, it does not have to be this way in the future.

With personalised medicine, we can use knowledge and new technologies to develop new treatments. Genetic knowledge of the characteristics of the disease and of the individual patient enhances our ability to diagnose diseases and provide more targeted treatment.

The development is well under way. A lot is happening internationally. In Denmark, the healthcare system and researchers are working to generate new knowledge and better results for patients. What is needed is strong collaboration, nationally and internationally.

If the Danish people are to benefit fully - for example, from new gene technologies - we need to make a collective national effort, within the healthcare system and research. Developments within diagnostics, treatment, research, infrastructure, ethics and safety need to go hand in hand.



It is a long haul, but an important one for Danish patients.

There is still a lot we do not know about genes. The new possibilities raise new clinical, legal and ethical questions. These need to be addressed. We have to be thorough and think carefully.

Therefore, in this updated and second version of the national strategy for personalised medicine, the Danish Government and Danish Regions have outlined a united way ahead. The Government and Danish Regions agree that the new possibilities must benefit the Danish people.

It is a wish we share with patient associations, universities, organisations, the Danish research community and the many professionals who have contributed to the implementation of the first strategy for the benefit of patients. For that we would like to thank them very much. Together we are now building on the strong national foundation that has emerged with the implementation of the first strategy. In Denmark, we now have to find new ways for the smart and secure use of data, and to jointly apply data for the benefit of the patients.

Magnus Heunicke  
Minister for Health

Stephanie Lose  
President, Danish Regions

# 1

## Joint effort



**Knowledge, technology, collaboration and ethics must interact in a new and better way. We will extend the joint strategy.**

Healthcare professionals have always aspired to give patients the most effective diagnostics and treatment, targeted to the individual patient and based on available knowledge. There is nothing new about that.

The new aspect is that, in personalised medicine, four basic elements within the healthcare system interact in a new way. The four elements are: knowledge, technology, collaboration and ethics. See Figure 1 below.

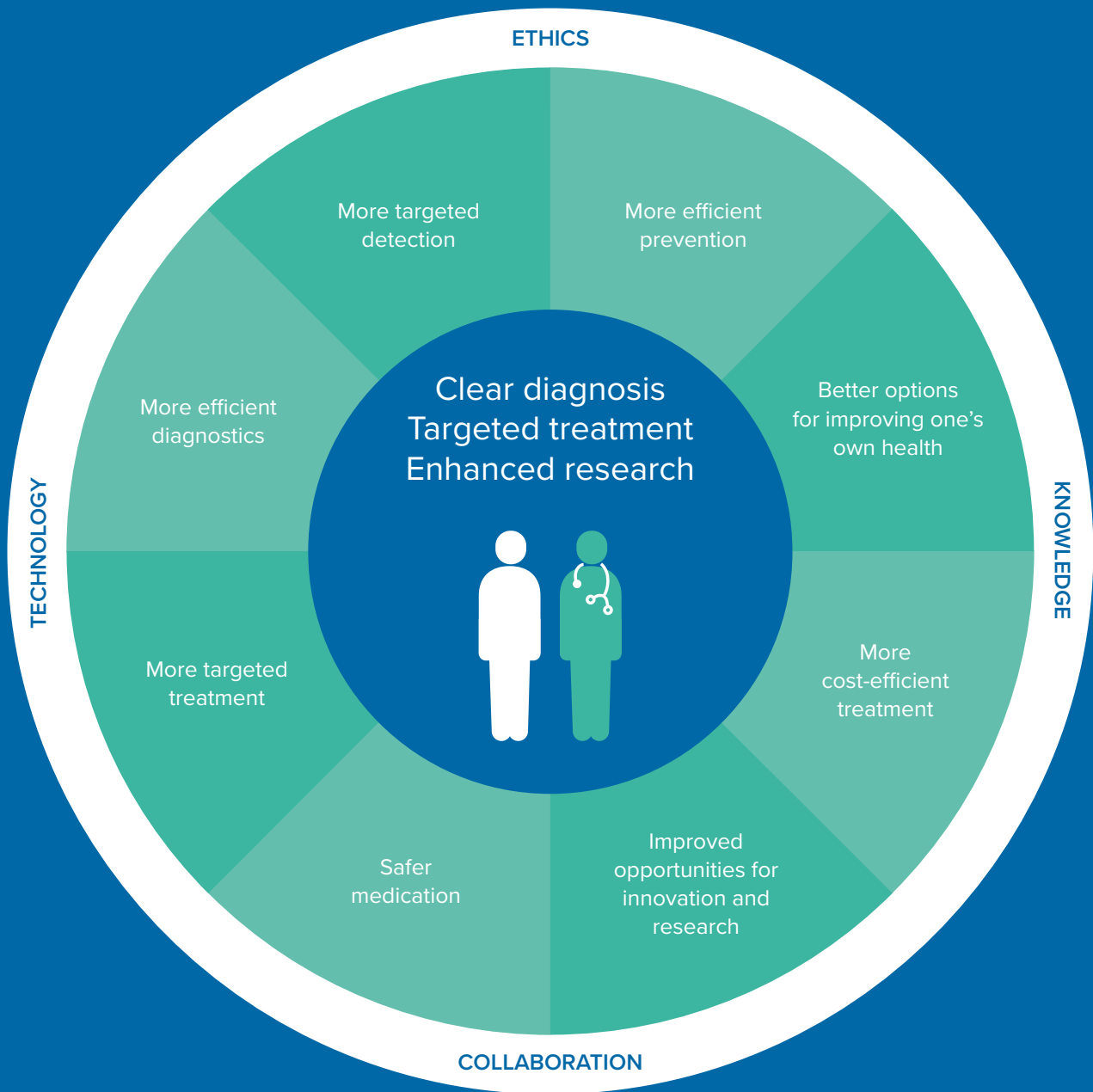
Our knowledge, for example about the significance of genetics, is expanding rapidly. We are learning more about the characteristics of patients and diseases. For example, we have learnt that in some cases different gene variants can lead to breast cancer. However, we have also learnt that the same gene variants do not necessarily develop into breast cancer in others.

In recent years, the price of technology and infrastructure has dropped. The healthcare system is able to offer the relevant patients a genetic analysis. Some people also choose to have a genetic analysis at their own initiative. Or to collect data so they can monitor their own health status.

Competent professionals are key to using genetic information and health data in new ways that are beneficial for patients. A large part of the information about genetics and other types of data is difficult to convert into specific knowledge about, for example, disease. And what can you do with the knowledge gained?

FIGURE 1

Personalised medicine – what do we want to achieve?



Ethical questions arise. In connection with the use of genetic information, you may find yourself in a situation where you have to decide whether the information received (for example, about a hereditary disease) may affect your family members. Or the doctor learns that the patient is at very high risk of developing a serious disease later in life. We must be able to handle these dilemmas.

The interaction between clinic, research, technology and ethics changes. This opens up new opportunities for creating a better healthcare system for the benefit of the patients. We have come a long way in recent years, and we need to keep collaborating to reach the shared goal: better diagnostics and treatment for patients.

Therefore, we will continue the development of personalised medicine in Denmark with an updated joint strategy.



### What is personalised medicine?

There are various terms to describe the diagnostics, prevention and treatment that can be more extensively customised to suit the needs of the individual patient. These include 'personalised medicine', 'precision medicine', 'tailored medicine' and 'targeted treatment'. The national strategy applies the term 'personalised medicine'.

Personalised medicine encompasses a development within the healthcare system in which diagnostics, prevention and treatment are more extensively customised to suit the individual patient's biology, physiology and personal preferences. It could be that an analysis of the genes might contribute to understanding why a patient has become ill and thus to finding the best treatment for the patient.

The overall goal is to be able to diagnose and classify diseases better in order to customise treatment to suit the needs of the individual patient. It may contribute to increasing the effect of treatment and reducing side effects or preventing disease.

This strategy focuses on personalised medicine, especially through the use of genetic information, to gain an insight into health and disease. It may be used for preventing, diagnosing and treating diseases, taking into account the particular biological conditions of the patient or the disease.

Comprehensive genetic analysis, including whole genome sequencing, pooling of data and the use of material from biobanks, is part of the realisation of the strategy. Other molecular biological knowledge and mapping, such as the analysis of our proteins, and other new technologies are advancing quickly and must be included in the long-term strategy. This is the case, for example, within the areas of diagnostic imaging, citizen generated data and patient-reported outcome.

### The Danish starting point

The development is already under way in Denmark – both within research and within the healthcare system.

We have used genetic information for a long time when advising on hereditary diseases. However, the underlying techniques are now increasingly being used to support more effective treatment, for example of cancer patients.

Many hospital departments use or request gene sequencing technologies. A majority of the medical specialities expect to use gene sequencing in the near future.

The ambition is for all relevant patients to be offered a genetic analysis of the same high quality, irrespective of where in Denmark they live. It is therefore very important for the continued work on personalised medicine in Denmark that relevant clinical activities and supportive infrastructure are consolidated and streamlined.

Many universities and hospitals are conducting research within this field, and research is being conducted throughout the entire value chain: from fundamental research into the genome to clinical patient-centered research. Research is also being conducted into the ethical and societal aspects.

Personalised medicine is generally undergoing a rapid development. If Denmark is to help further the development, and the Danish people are to benefit from new technologies, collaboration and coordination of the increasing activity are required.

The use of data will increase in order to keep up with the rapid development. It is all about realising the potential by creating a link between our existing knowledge about the diseases in the population and the knowledge about genetics.

Researchers must have secure, quick and easy access to pseudonymised data, so that new knowledge and new treatments can be developed for the benefit of patients. Data and knowledge must be shared in a secure manner to enable doctors to make a more precise diagnosis and target treatment more quickly than is the case today.

### **The development 2017-2020**

The first national strategy for personalised medicine 2017-2020 was launched based on comprehensive preparatory work involving a large number of experts and stakeholders.

Many of the central aims of the strategy have been reached. These include: the establishment of a national genome centre under the Danish Ministry of Health with responsibility for supporting the development of personalised medicine in Denmark; and the development of a national infrastructure for personalised medicine, which will ensure that relevant patients obtain equal access to genome sequencing. This development has taken place within the framework of the Danish National Genome Center in close collaboration with relevant operators in the healthcare system, the research community etc. A national collaboration to ensure that patients benefit directly from genetic analysis is a new focus, nationally and internationally.

In close connection with the first strategy period for personalised medicine, the Danish Ministry of Health and Danish Regions have initiated an analysis of the biobank area in Denmark. The analysis will present scenarios for a national strategic initiative to strengthen and consolidate the biobank infrastructure in Denmark so that the biobanks can support the development of personalised medicine. The analysis will be completed in 2021.

As part of the support of the infrastructure for personalised medicine, the regions and the universities have joined forces to establish regional data support centres. The regional data support centres will be certified environments for the use of data for research and in clinical practice with great focus on data security. The regional data support centres are part of an ecosystem consisting of general practitioners, hospitals, municipalities, government and joint regional initiatives, and universities.

To support the regional data support centres and the rest of the infrastructure, Danish Regions and the Danish Ministry of Health are collaborating on the project, 'Én fælles indgang til sundhedsdata' (A single point of entry to health data). The vision is that the individual researcher should be able to access one site where it is easy to gain an overview of health data, obtain information and guidance on framework and requirements, and make a digital application for use of health data for research purposes from relevant authorities.





## **Personalised medicine for more people**

Denmark and the other Nordic countries have made substantial progress in the development of personalised medicine.

Patients with genetically conditioned diseases will experience an improvement in their treatment as genetic diagnostics gradually become a routine tool. In the long term, other patients must also benefit from more precise diagnostics, prevention and treatment. These could be patients with common chronic diseases such as diabetes or COPD. For many patients, genetic analysis in the development of personalised medicine is not enough. Linkage to other data is crucial. It is a comprehensive task that requires technological development and innovation. Denmark is a global leader within research and infrastructure that may support the development of personalised medicine so that today's health research may become tomorrow's treatment advances.

## **International experience**

Denmark has come a long way and is a global leader in the field of personalised medicine. However, a lot of inspiring work is being done in neighbouring countries. There are different approaches to the area, and the individual countries attach importance to different elements in their strategies.

Denmark may further develop the experience gained by other countries. For example:

- Dialogue with patients and the population about, e.g., the ethical and legal aspects is crucial
- It is important to have a joint strategy and governance
- Collaboration on technological infrastructure is required
- Collaboration models and the presence of the necessary competences are prerequisites for success
- There must be international and national collaboration to ensure that researchers have access to relevant data resources, if future patients are to benefit from the development to a satisfactory degree

However, Denmark follows its own path. We have our own positions of strength. We continue to build on a foundation with a strong tradition of collecting data and knowledge and using it actively in clinical practice and for research. We also have a collaborative spirit in clinical communities within specialities and fields such as cancer to discuss data and results.

At the same time, we have to be aware that the field of personalised medicine is constantly developing. In connection with the implementation of the strategy, we will therefore still look to the countries around us. We believe that there is a need for international discussion and feedback to ensure inclusion of the latest knowledge within the field.



## International experience with personalised medicine

### Norway

'Nasjonal strategi for persontilpasset medisin i helsetjenesten (2017-2021)' focuses on national collaboration, development of competencies and a joint technological infrastructure. An expert committee on personalised medicine follows up on the national strategy, and in 2020 a legal clarification was carried out that paves the way for the establishment of a national genome centre.

### Finland

According to the strategy 'Improving health through the use of genomic data (2015-2020)', a national genome centre, a national cancer centre and a coordinated approach to biobanks form the framework of the Finnish work. In October 2020, the establishment of the genome centre is awaiting a number of legal amendments.

### Sweden

In Sweden, there are relevant and strong research constellations within genomic research and personalised medicine at the Swedish universities and in the healthcare system. Since 2018, they have been gathered under Genomic Medicine Sweden, where the goal is to bring genomic innovation into clinical practice and to ensure implementation of a permanent infrastructure for personalised medicine in Sweden.

### England

The English government's strategy 'The future of healthcare' (September 2020) focuses on diagnostics/treatment, prevention and research. It is based on 'The 100,000 Genomes Project 2014-2017', which is run by the state-owned company, Genomics England, and now expanded to 500,000 genomes. Other infrastructures include Biobank UK and Accelerated Disease Detection Challenge.

### EU

In 2018, EU launched a European collaboration to develop an infrastructure aimed at supporting tailored diagnostics, prevention, treatment and research. This will take place by connecting national genome databases so that in 2022 there will be access to the genomic data of at least 1 million Europeans in an ethically responsible manner and without data being able to exit the system. The collaboration will also support research collaborations and look for new health and technological development.

### USA

A central element in the American 'Precision Medicine Initiative' (initiated in 2015) is a new model for patient-based research aimed at accelerating biomedical discoveries and providing clinicians with new tools, knowledge and treatments. 350,000 research participants have been recruited and a research platform is being tested with significant focus on COVID research (June 2020).

# 2

## Principles and focus areas of personalised medicine in Denmark

The National Strategy for Personalised Medicine 2017-2020 paved the way for the use of personalised medicine in Denmark. During this strategy period, personalised medicine must be implemented in the healthcare system for the benefit of citizens and patients.

We have formulated six principles that will underpin this development. It is important to be 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 aim to guide the work on personalised medicine. The principles aim to ensure that we work within the same framework.

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



## The strategy's six principles

- 1 The Danish efforts within the field of personalised medicine must focus on patients. Genome sequencing must be used for treatment purposes and in research projects.
- 2 Confidentiality, the individual's right to decide, protection of information and research ethics approval are paramount.
- 3 The use of personalised medicine as a standard provision in the healthcare system must be evidence-based and economically sustainable.
- 4 Genome sequencing and data processing must be rooted 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 must be nationwide.

## National strategy – focus areas at a glance

The development and implementation of personalised medicine in the healthcare system require simultaneous initiation and development of several initiatives. Many areas must work together. The Government and Danish Regions have therefore agreed on seven strategic focus areas. Together, they will guide the work in the coming years.



### EXAMPLE

#### Psychiatric disorders

Within the field of psychiatry, there have been quantum leaps in the last twelve years vis-à-vis understanding the hereditary causes of psychiatric disorders. Whole genome sequencing of the human genome can explain severe psychiatric illness in both children and adults, including those with no neurological or paediatric disorders.

Psychiatric genetics has also revealed how all humans are more or less predisposed to psychiatric disorders, and this predisposition shapes our differences. This has helped destigmatise psychiatric illness and given patients a new basis for quicker and better diagnostics and more targeted treatment.

# Strategic focus areas



## PATIENTS AND CITIZENS MUST BE INVOLVED

The development of personalised medicine will depend on information about treatment and research for Danish patients and citizens. Openness and dialogue with the public are therefore imperative. The involvement of patients and the public is required, and information sharing, communication and involvement are pivotal.



## 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, to conduct genome sequencing and to register, process and share data. The nationwide infrastructure must accommodate both treatment and research of significant societal importance. It must also benefit from, and interact with the existing central and local infrastructures already in place in the healthcare system and research community.



## TOOLS AND COMPETENCIES TO USE GENETIC DATA

It is important for future clinical practice to be based on reliable evidence. A knowledge base and a permanent, professional collaboration must be set up to work on the significance of genetic differences for use in everyday clinical practice. Relevant healthcare professionals must be capable of using genetic information and other health data to inform patients and relatives about the contents and meaning of patient treatment. It is also important for the development of the area to ensure 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 to become an important Danish research area. There are promising possibilities within public-private collaboration on new treatments – particularly new medicines – that will benefit patients.

The governance structure must ensure a clear framework for collaboration between public researchers, clinicians, patients and private companies. The governance structure is a prerequisite for strong, 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 societal importance.



## **RESEARCH INTO PERSONALISED MEDICINE MUST BE INTERNATIONAL AND DEEPLY INTEGRATED IN THE HEALTHCARE SYSTEM**

Treatment, research and development are inseparable. It is our research into the majority that enables us to make a difference for the individual. There must be a clear, secure framework for cooperation between clinical practice and research, including a framework for the use of data, nationally and internationally. Research and development must be based on clinical challenges, relevant patients and risk groups, and disease areas. The costs and effects of projects within the strategy must be evaluated to gain knowledge about cost-effectiveness.



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

It is essential not only to ensure appropriate protection of the safety, health, integrity and right to self-determination of study subjects and patients, but also to ensure that any advances in the healthcare system benefit patients. Thus, it is essential for the trust in the Danish development of personalised medicine that any efforts entail comprehensive information efforts and a reliable ethical, legal and data safety-related approach. We must ensure the continuous development of knowledge about the ethical, legal and societal aspects associated with the implementation of genome sequencing and personalised medicine in the healthcare system.



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

The work must be nationwide and open. The national coordination must ensure balanced development in the area of personalised medicine, taking into account relevant concerns and facilitating decentralised implementation in the healthcare system. A key concern in this respect is to ensure an appropriate balance between a long-term national strategy and locally embedded efforts.



The work with the strategic focus areas is based on the previous strategy period and will build on the existing structures and efforts within, for example, the healthcare system, research and education.

The Danish Ministry of Health and Danish Regions will follow up on the progress within the seven strategic focus areas.

#### EXAMPLE

##### Rare diseases

In Denmark, the collective term 'rare diseases' is used to refer to a number of diseases which, in addition to being rare, are also congenital, hereditary, chronic, complex and serious. Consequently, patients with rare diseases are often subject to lengthy workups with many successive analyses.

By using whole genome sequencing, in many cases it is now possible to get it right the first time, and the workup and treatment of the patient can therefore take place much more quickly.

Reasons for delayed development - for example, in the case of children - may include genetic changes. Whole genome sequencing facilitates identification of the genetic change that causes the disorder and more targeted treatment and follow-up for the child and the family.



# 3

## The focus of the strategy - and the way ahead

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

The Government and Danish Regions agree that the Danish strategy for personalised medicine in the healthcare system should still focus on patient and clinical needs. More focus should be on diseases and risk groups as a basis for research and development.

In the short term (2021-2022), the Government and Danish Regions will collaborate on the implementation of the strategy in several areas. This will take place in three parallel phases

1. Initial use of the infrastructure for whole genome sequencing
2. Research infrastructure for personalised medicine
3. Further development of personalised medicine and inclusion of several data sources

### PHASE 1

#### Initial use of the infrastructure for whole genome sequencing

- Establishment of a steering committee for the implementation of personalised medicine in Denmark
- Further development and commissioning of a secure, joint and national technological infrastructure for genome sequences and expansion of data storage
- 60,000 whole genomes sequenced in the healthcare system by 2024
- Reporting of data from comprehensive genetic analysis in the healthcare system for the national genome database

### PHASE 2

#### Research infrastructure for personalised medicine

- Implementation and further development of a national research infrastructure for personalised medicine
- Use of the research infrastructure in research and development projects
- Consolidation of the regional data support centres for personalised medicine

### PHASE 3

#### Further development of personalised medicine and inclusion of several data sources

- Analysis of the possibility of including more data sources in the personalised medicine infrastructure



There will be ongoing involvement of patients, citizens and professionals, and the development will take place in dialogue with the stakeholders. There will be continuous focus on the ethical and legal aspects.

There is a large potential associated with the use of genetic information for diagnostics, treatment and prevention within many disease areas. The Government and Danish Regions agree that a collective Danish effort within the field of personalised medicine must focus on research and genome sequencing within disease areas and risk groups. In the long term, the ambition is to expand the effort with more data sources and 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 and relatives
- Those associated with a significant genetic component, also having 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 treatments

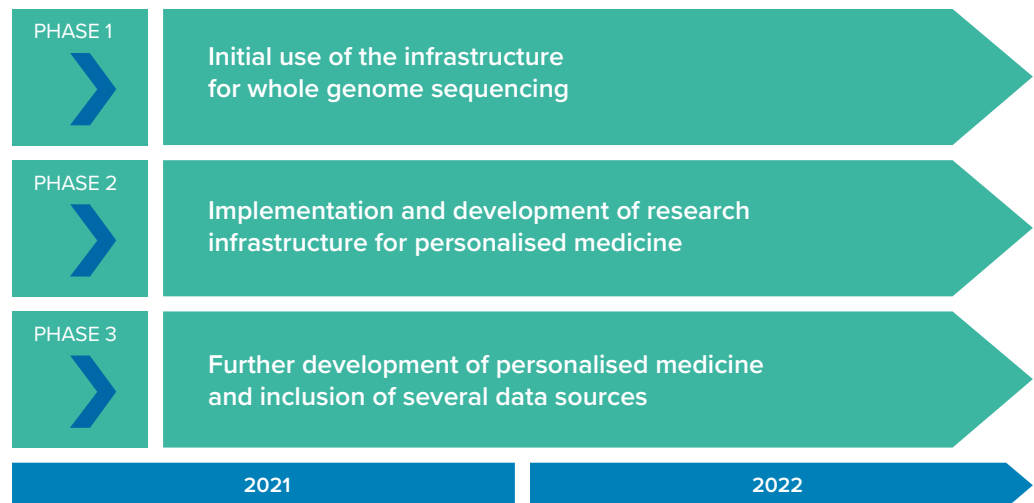
There must be equal access to genome sequencing throughout Denmark for relevant patient groups, regardless of where they live.

Areas in which Denmark is expected to deliver high-quality research should also be a priority. For example, potentials are anticipated in research and genome sequencing within a number of fields such as cancer, psychiatry, infections as well as autoimmune disorders and rare diseases.

The purpose is for the overall infrastructure to constitute a shared national resource and research infrastructure with access to research on equal terms. All relevant research projects and clinical activities, within and outside the strategy, must be able to use the organisational and technological infrastructure. Thus, the infrastructure is intended to accommodate clinicians and researchers in general.

FIGURE 2

Illustration of the implementation of the different phases of the strategy





# 4

## Implementation of the strategy – transparent governance

The realisation of this strategy for personalised medicine in Denmark requires clear and transparent governance and collaboration between all parties within the healthcare system and the research community.

This strategy focuses on implementing the national infrastructure for whole genome sequencing, and in the long term this will be expanded to include more data sources. What is needed, therefore, is an unambiguous governance structure to facilitate the realisation of the phases and strategic focus areas described, ensuring a proper balance between central and local governance, development and implementation.

### **Governance and the Steering Committee for the implementation of personalised medicine**

The Danish Ministry of Health and Danish Regions are responsible for ensuring national collaboration and progress within the phases and strategic focus areas described. The parties may agree on specific goals and initiatives for this.

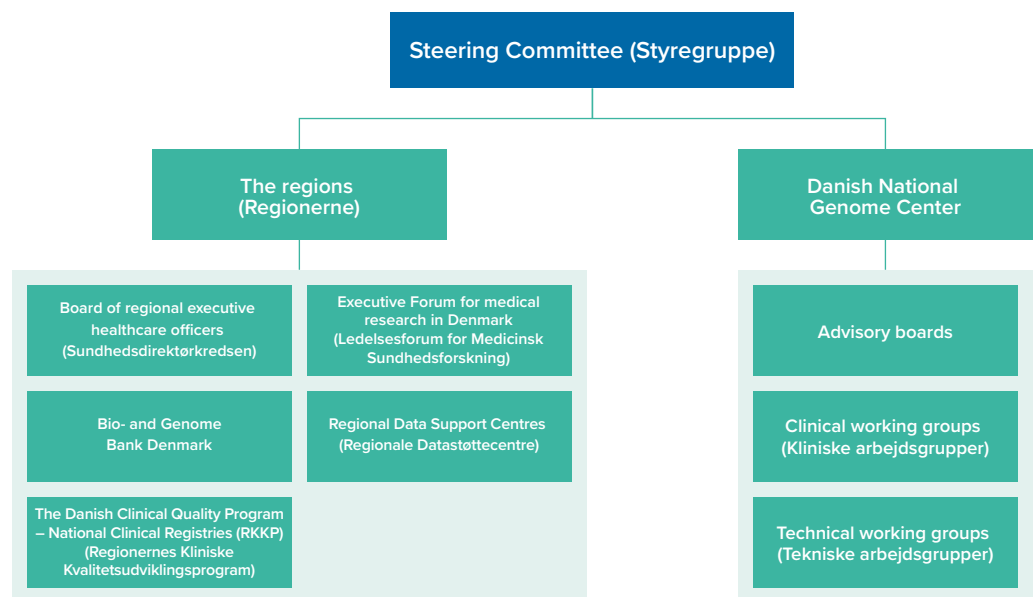
The implementation of the strategy will be based on a Steering Committee for the implementation of personalised medicine. See Figure 3. The Steering Committee will ensure a clear joint public responsibility for, and collaboration on the development, implementation and operation of the national infrastructure for personalised medicine with special focus on whole genome sequencing during the strategy period. (2021-2022).

The Steering Committee will consist of representatives from the Danish Ministry of Health, the regions, the universities and the Danish National Genome Center. The Danish Ministry of Health will chair the Committee, and the Danish National Genome Center will provide secretariat services for the Steering Committee.



FIGURE 3

Steering Committee for the implementation of personalised medicine





### **Regional clinical activity and research – infrastructure and support**

The regions are responsible for carrying out whole genome sequencing of selected patient groups in collaboration with the Danish National Genome Center. In addition to the daily use of personalised medicine in clinical practice, the regions are responsible for operating four regional data support centres, which may support the individual research project: for example, in the areas of research design, analysis methods, approval procedures and identification of collaboration partners. The regions have also established joint national governance and principles for The Danish Clinical Quality Program – National Clinical Registries (RKKP) (Regionernes Kliniske Kvalitetsprogram) and Bio- and Genome Bank Denmark (Regionernes Bio- og GenomBank).

### **Danish National Genome Center (see also Chapter 5)**

The Danish National Genome Center develops and operates a joint, national infrastructure for personalised medicine, which provides doctors and researchers with access to genome sequencing and storage of information in a National Genome Database. The Center supports the continued development of personalised medicine to benefit patients in collaboration with the regions and the entire Danish healthcare system, research institutions, patient associations etc. The Danish National Genome Center coordinates collaboration on the strategy's initiatives: for example, by providing secretariat services to the Steering Committee for the implementation of personalised medicine and other relevant fora.



# Danish National Genome Center

The ability to use genetic information securely together with other knowledge from registers, databases and information sources is key to the realisation of the potential for personalised medicine.

The Danish National Genome Center was therefore established by statute on 1 May 2019 as part of the implementation of the first national strategy for personalised medicine (2017-2020).

The purpose of the Danish National Genome Center is to support the continued development of personalised medicine to the benefit of patients in collaboration with the regions and the entire Danish healthcare system, research institutions, patient associations etc. In the short term, the Center will develop and operate a joint, national infrastructure to ensure that doctors throughout the country have access to whole genome sequencing and storage of information in a National Genome Database. The Danish National Genome Center will also develop a national research infrastructure for personalised medicine.



**In several areas, the Danish National Genome Center Act has enhanced Danish efforts in the field of personalised medicine.**

1. Ensuring that relevant patients can benefit from personalised medicine immediately is a priority. For patients, this means that they will have the same provision, regardless of where in Denmark they are hospitalised.
2. The collection, storage and use of genetic data and other information from patients in Denmark will be based in the public sector, and the information will be stored with the highest degree of security.
3. Patients' self-determination has been strengthened. Partly because the patients have to provide consent for all activities involving comprehensive genetic analysis. Partly because patients have a new right to decide that their genetic data stored at the Danish National Genome Center must not be used for health research.
4. The statutory purpose limitation means that information stored by the Danish National Genome Center can only be processed for purposes relating to the healthcare system or for scientific or statistical purposes. Thus, the information cannot be used, for example, in insurance or pension cases.



In combination with other data, the infrastructure must provide more knowledge of the patients' genes and causes of disease. The national collection of knowledge will make it possible for the doctors to make more precise diagnoses more quickly. In the long term, it is hoped that it will help us develop better treatments targeting the individual patient. The Danish National Genome Center supplies the Danish healthcare system and research, and it ensures that extensive genetic analysis can be made with the same high quality for all relevant patients in Denmark. It also enables doctors and health researchers, making a joint effort, to have better conditions for improving the treatment of future patients.

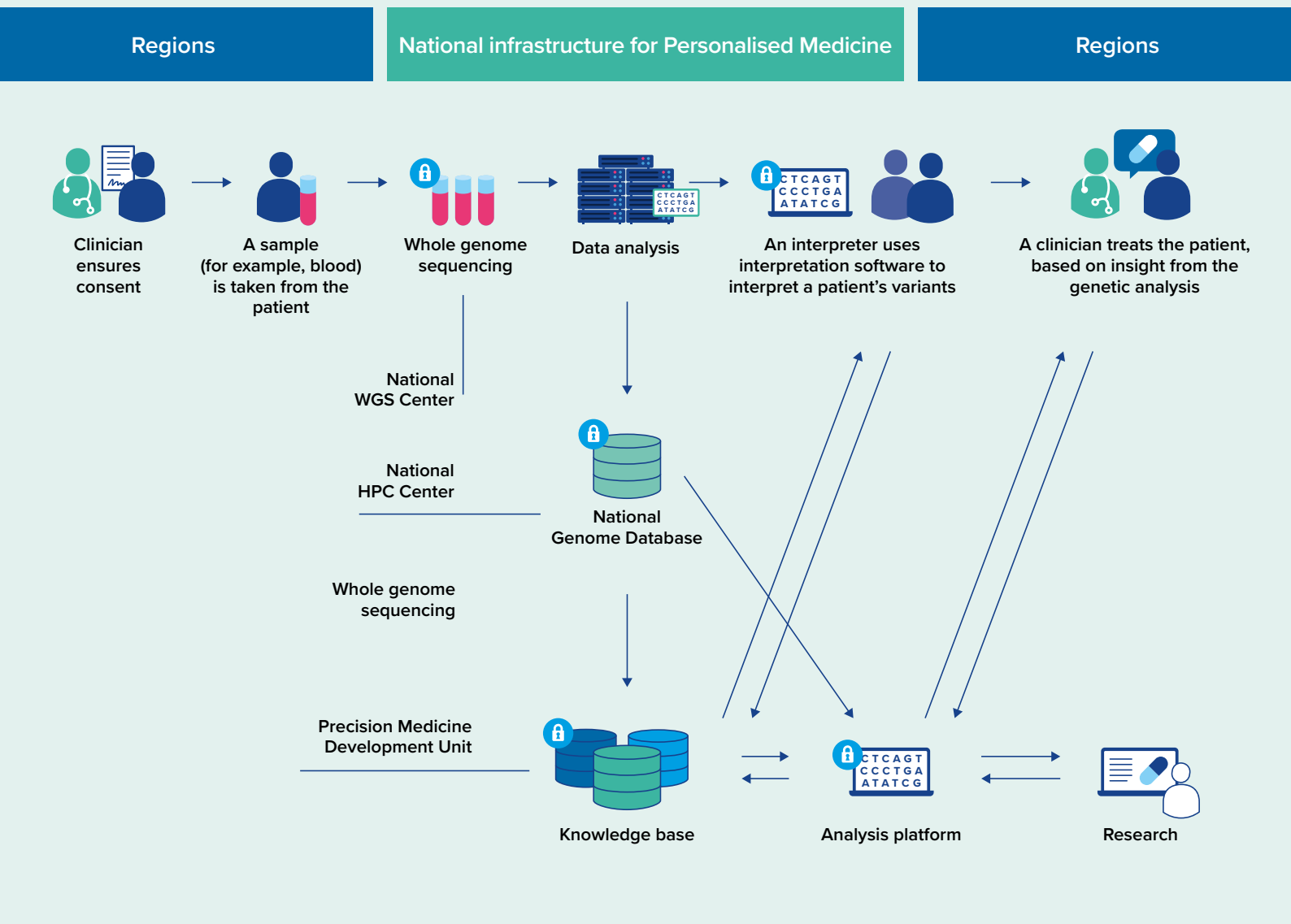
### **National infrastructure for personalised medicine**

The Danish National Genome Center develops and operates Denmark's national infrastructure for personalised medicine, consisting of a National Whole Genome Sequencing Center and a National High Performance Computing Center (supercomputer system), including a National Genome Database for processing and storage of genomic data etc. See Figure 4. The infrastructure is designed on the basis of principles of security-by-design and scalability with respect to capacity as well as technology.

There is a need for a powerful national supercomputer system, since our genetic material, although taking up very little space in our cells, contains huge amounts of information. It is therefore an extremely demanding computer task to search the thousands of genomes and gene variants that the supercomputer's databases need to contain. It is also through the supercomputer's databases that a more precise mapping and knowledge of the individual patient's genetic profile can be generated in relation to the patient's treatment. It is therefore a ground-breaking system enabling new interaction between patient treatment and research, which is crucial when it comes to developing personalised medicine.

FIGURE 4

National infrastructure for personalised medicine



The Danish National Genome Center is responsible for developing and implementing specific tools, including a national interpretation platform and knowledge databases, aimed at providing better support for the doctors' treatment of individual patients in hospitals and for continued research into personalised medicine. Over time, the National Genome Database will constitute a significant research resource that can contribute to the further development of personalised medicine in Denmark.

### **Grant for infrastructure and increased use of extensive genetic analysis within the healthcare system**

At the end of 2019, the Novo Nordisk Foundation awarded DKK 992 million (EUR 133 million) to kickstart the infrastructure of the Danish National Genome Center on the basis of an ambitious and clear roadmap.

The grant means that Denmark in one go has been able to strengthen the overall effort within the field of personalised medicine to a level, which it would otherwise take a long time to reach in the Danish healthcare system. By 2024, up to approx. 60,000 patients can look forward to better diagnostics and more targeted treatment on the basis of genome sequencing.

### **The further development of personalised medicine**

The Danish National Genome Center supports the further development of personalised medicine and coordinates collaboration on the initiatives of the strategy: for example, by providing secretariat services to the Steering Committee for the implementation of personalised medicine and other relevant fora.

In the long term, the Danish National Genome Center will support the further development of personalised medicine by making it easier for doctors and researchers to include genetic data, new technology and other knowledge in research that will give us a better understanding of disease and pave the way for the development of new or improved treatments for the benefit of future patients.

There is a great demand for researchers, clinicians and authorities in the context of combining different data sources. Consequently, the Danish National Genome Center has a shared task with other stakeholders in terms of the further development of infrastructure and tools for more efficient utilisation of health data across the healthcare system etc.

Research and development will be closely linked to the treatment effort. It will ensure that resources are applied where they benefit patients the most.



# Finances

## Principles for funding

Currently, the use of genetic analysis in the healthcare system is mainly financed by the regions and hospitals that are involved in the area within the existing economic framework.

Research within this area is financed primarily by public research funds and private contributions. The national strategy for personalised medicine does not change this. The primary purpose of the strategy is to ensure a common direction, coordination and consolidation of the overall effort and to establish the framework for a major strategic effort. For an extraordinary increased use of genetic analysis within research and the healthcare system, the raising of private funds is key. At the end of 2019, the Novo Nordisk Foundation granted DKK 992 million (EUR 133 million), for example for infrastructure and the genome sequencing of (approx.) 60,000 Danish patients during the period 2020-2024 within the framework of the Danish National Genome Center.

It is assumed that the Government, the regions and private foundations finance the strategy jointly, but with clearly defined and separate areas of responsibility.

### General principles for funding:

- The Government funds the operation of the Danish National Genome Center and the execution of relevant authority tasks, including tasks within ethics, law, data security and accountability etc. From 2021 and onwards, the government grant for the Danish National Genome Center has been made permanent to the tune of approx. DKK 30 million (EUR 4 million) annually under the Danish Finance Act. In addition, the activities of the Danish National Genome Center may be paid for by self-funding activities.
- The regions contribute existing funds for the national strategy by prioritisation within the existing economic framework. With this strategy, no new funds are appropriated for standard treatment in clinical practice etc. The strategy may involve both potential cost reductions and additional expenses in the healthcare system.
- For example, private foundations may grant support and donations for infrastructure, research activities and general citizen-centric communication and education activities.

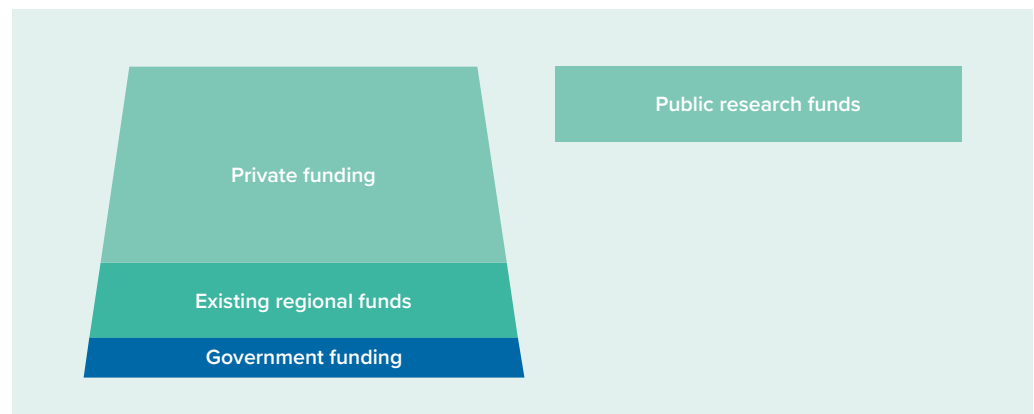
Authority tasks and data liability must thus be carried out and funded by the public sector.

Co-funding by private foundations does not grant the foundations special access to the data generated in connection with the implementation of the strategy.



FIGURE 6

Sources of funding



The primary sources of funding for the strategy are illustrated in Figure 6. The extent of infrastructure, research activity etc. as part of the strategy will depend, for example, on the size of any foundation-financed funds. Research activities within personalised medicine funded by other public research funds may also use the infrastructure.

# Do you need more information?

**The Danish Ministry of Health**

[www.sum.dk/Sundhedsprofessionelle/Personligmedicin.aspx](http://www.sum.dk/Sundhedsprofessionelle/Personligmedicin.aspx)

**Danish Regions**

[www.regioner.dk/sundhed/temaPersonligmedicin](http://www.regioner.dk/sundhed/temaPersonligmedicin)

**Danish National Genome Center**

[www.ngc.dk](http://www.ngc.dk)

**Norway**

<https://www.helsedirektoratet.no/rapporter/strategi-for-persontilpasset-medisin-i-helsetjenesten>

**Finland**

<https://stm.fi/en/personalized-medicine>

**Sweden**

<https://genomicmedicine.se/en/>

**England**

[www.genomicsengland.co.uk](http://www.genomicsengland.co.uk)

**European 1+ million genomes initiative**

[ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative](http://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative)

**All of us**

<https://allofus.nih.gov/>

**Nordic alliance for clinical genomics**

<https://nordicclinicalgenomics.org/>

**Council of Europe**

[www.coe.int/t/dg3/healthbioethic/default\\_en.asp](http://www.coe.int/t/dg3/healthbioethic/default_en.asp)

**European Alliance for Personalised Medicine**

[www.euapm.eu](http://www.euapm.eu)

**Global Alliance for Genomics and Health (GA4GH)**

<https://www.ga4gh.org/>

**World Health Organization**

[www.who.int/topics/genomics/en](http://www.who.int/topics/genomics/en)

**France Genomique**

<https://www.france-genomique.org/?lang=en>

**Australian Genomics Health Alliance**

<https://www.australiangenomics.org.au/>



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