Personalised medicine strategy

2025 - 2027

MINISTRY OF THE INTERIOR
AND HEALTH OF DENMARK

DANISH
REGIONS

Contents

Personalised medicine - patient centricity for future treatments

In Denmark, significant progress has already been made in personalised medicine. Thanks to genetic information, we can offer patients more precise and targeted treatments that work better and are more personalised.

This is partly because the government and Danish Regions took the first steps in 2016 with a joint strategy for personalised medicine. Since then, collaboration between the healthcare service, the research community, patient organisations and universities has been strengthened. And in 2019, the Danish National Genome Center was established with support from the Novo Nordisk Foundation. The ambition was clear: to give up to 60,000 patients access to better diagnostics and treatment based on their genetic profile.

It's a strong starting point that we are proud of. This has put Denmark on the world map and made us one of the leading countries in personalised medicine. We need it to stay that way.

But things are moving fast. Not just in Denmark, but around the world. Therefore, it's no longer enough to think of personalised medicine as only genomes and rare disease treatments alone. Personalised medicine is much more than that.

Personalised medicine is about the entire patient pathway and offers opportunities to enhance the patient experience across the wider healthcare service. That is why personalised medicine needs to become more widespread so that more patients can benefit from its opportunities. This places demands on both patients and healthcare professionals who need to be equipped to handle new technologies, data and treatments.

The volume of health data within and outside the healthcare service is growing exponentially. Denmark has a unique and strong position with our health data and biobanks, which form a solid foundation for both treatment and research. Therefore, we have the opportunity to become a world leader in the development and application of personalised medicine in the healthcare service.

At the same time, personalised medicine can contribute to a more sustainable and cost-effective healthcare service. By targeting treatment, we can better avoid overtreatment, side effects and unnecessary hospitalisations, which frees up resources and creates more value - both for patients and society.

There is an ongoing focus on transforming the healthcare service to meet the new needs and opportunities presented by personalised medicine. To realise the potential, it's crucial that the healthcare service has the skills and capabilities that personalised medicine requires. Employees must be equipped to handle new technologies, complex knowledge and dialogue with patients, including genetic analyses. Research can help increase our knowledge of what treatments work while creating a good working environment with high professional quality.

Personalised medicine must be part of everyday clinical practice. Prioritisation is therefore necessary to ensure a sustainable healthcare service in which resources are fairly distributed.

Furthermore, we need to address the legal barriers that delay development. Legal barriers and bureaucratic red tape make it unnecessarily difficult for researchers, companies and healthcare professionals to share and use data - even if it benefits patients. Health data is often scattered in silos and inaccessible across sectors, which slows innovation and delays new treatments.

The Danish government has already taken vital steps with legislative changes to create a more flexible framework for the responsible use of health data. With this strategy, we strengthen our ambition to make much better use of health data. Making it easier and faster to use health data for research and development with a clear framework that continues to ensure citizens' trust and rights.

Overall, the strategy should contribute to:

Putting the patient first: Ensure that the patient’s preferences, values, and life situation are actively taken into account in the prevention and treatment of disease.

Strengthen the framework for personalised medicine research: Create a stronger framework for personalised medicine research so that new knowledge is quickly translated into benefits for patients.

Make Denmark a leader in advanced therapies: Reinforce Denmark’s position as one of the leading European countries in developing, testing, and offering advanced therapies as part of patient care, giving patients faster access to the most effective solutions.

Free up resources and improve the quality in the healthcare service: Improve the quality of care and ensure more cost-effective use of the healthcare service’s resources through data-driven targeting of prevention and treatment.

Strengthen Denmark’s biobanks and health databases: Ensure that data can be used even more effectively and across sectors to benefit patients and for world-class research.

Use healthcare data and artificial intelligence wisely: Better utilise the potential of Danish health data and artificial intelligence to tailor treatments that work for the individual.

Spread personalised medicine across the healthcare service: Give far more patients access to the possibilities of personalised medicine.

Denmark already has a unique starting point. We have innovative and robust research environments, an internationally leading life science industry, and a long tradition of close, trusting collaboration across public and private actors. We must ensure that Denmark remains attractive to those who develop the treatments of the future, not least within Advanced Therapy Medicinal Products (ATMPs).

The first ATMPs are already in use, but their development needs to be improved. Complex regulation, lack of national coordination and the need for new payment models prevent new treatments from reaching patients quickly. We must take political responsibility to change this. Denmark should be the country where new, advanced treatments can be utilised quickly to benefit both patients and the healthcare service. At the same time, we need a stronger basis for assessing new medicines and treatments so that we prioritise those that benefit patients most.

With this strategy, the government and Danish Regions present an ambitious plan for the future of personalised medicine. Developed in close collaboration with the healthcare service, research, patient organisations and industry, it targets exactly where we can create the most value for patients and society.

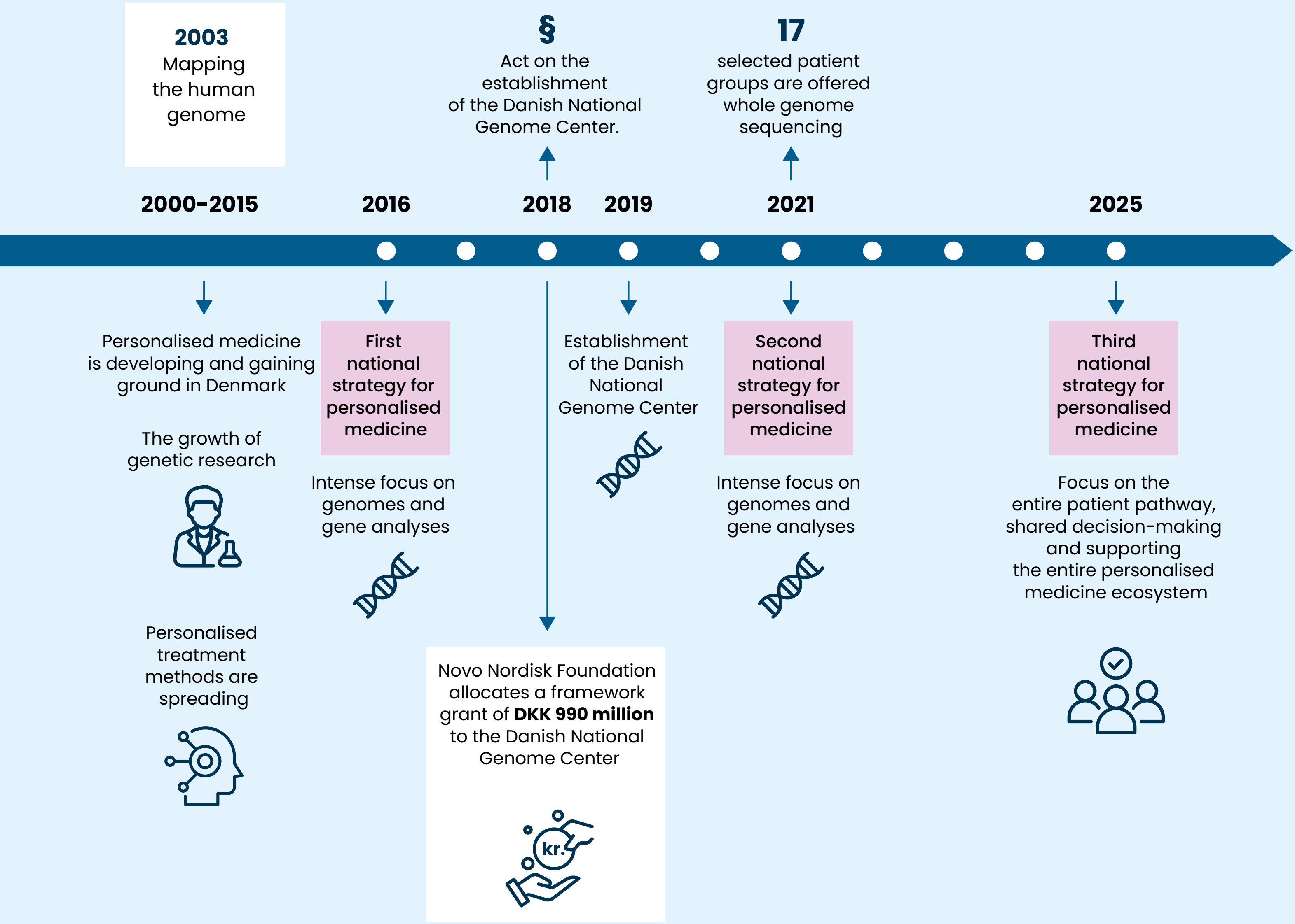
Our ambition is for Denmark to be an international frontrunner in personalised medicine. This can contribute to a healthcare service that both prolongs and improves quality of life, while ensuring more sustainable utilisation of the healthcare service's resources.

Sophie Løhde,
Minister for the Interior
and Health

Anders Kühnau,
Chairman of
Danish Regions

The development of personalised medicine in Denmark

With the government and Danish Regions' two previous national strategies for personalised medicine, we have set the direction for the development of personalised medicine in Denmark. In 2016, in collaboration with Danish Regions and the Novo Nordisk Foundation, the Danish government decided to establish the Danish National Genome Center to enable the Danish healthcare service to analyse citizens' genomes and use this knowledge in the detection, prevention, diagnosis and treatment of diseases. With the establishment of the Danish National Genome Center in 2019, not only has a central knowledge database that stores genomes been created, but an infrastructure for anyone anywhere in Denmark to have their complete genetic makeup mapped using a blood sample. This has created a firm foundation for the development of personalised medicine in the future.



2003
Mapping the human genome

2000–2015

Personalised medicine is developing and gaining ground in Denmark

The growth of genetic research

Personalised treatment methods are spreading

2016

First national strategy for personalised medicine

Intense focus on genomes and gene analyses

2018

§
Act on the establishment of the Danish National Genome Center.

Novo Nordisk Foundation allocates a framework grant of **DKK 990 million** to the Danish National Genome Center

2019

Establishment of the Danish National Genome Center

2021

17
selected patient groups are offered whole genome sequencing

Second national strategy for personalised medicine

Intense focus on genomes and gene analyses

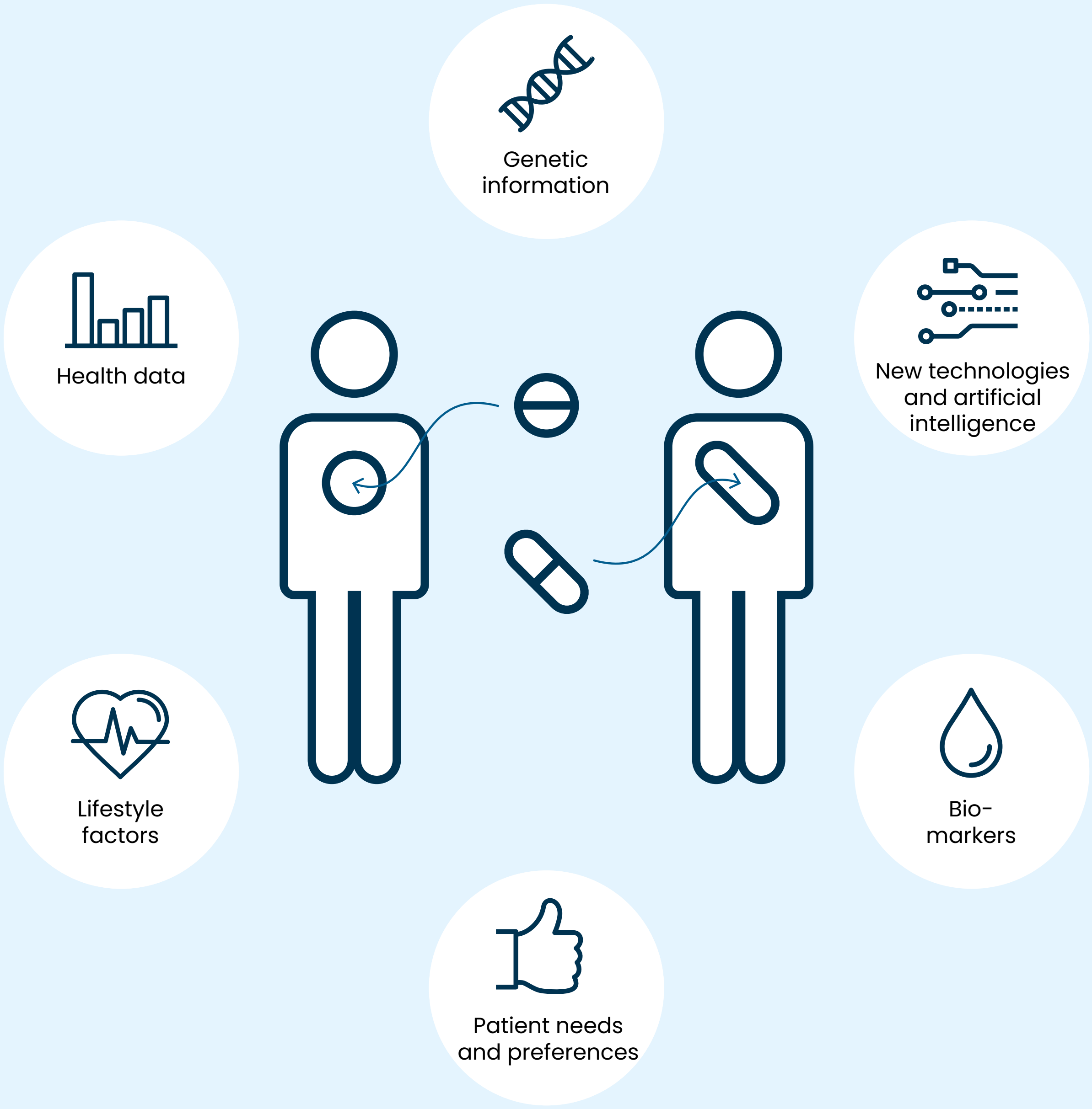
2025

Third national strategy for personalised medicine

Focus on the entire patient pathway, shared decision-making and supporting the entire personalised medicine ecosystem

Personalised medicine

Personalised medicine is about tailoring health interventions to the individual, which includes early detection, prevention, diagnosis, treatment and follow-up. The approach is based on close collaboration with the patient and on the individual's unique profile, including genetics, lifestyle, and disease progression. By utilising health data and new technology, more precise and effective treatments can be developed to best suit the individual.



Genomic analysis is central to personalised medicine because it maps an individual's genetic code, which significantly impacts how we respond to diseases and treatments. However, personalised medicine offers many more opportunities to better target prevention and treatment to the individual, including better use of health data and new advanced technologies.

Personalised medicine should be understood as an approach in the healthcare service that focuses on the entire patient pathway and puts the patient at the centre of their own treatment. We are in a place where rapid technological developments within and outside the healthcare service are giving us new opportunities to target prevention and treatment, and empower patients to take control of their own health.

In the future, we must ensure that we make use of the opportunities personalised medicine offers, both to create better treatment for individual patients and to support a sustainable healthcare service. A broader understanding of the concept is therefore needed. With this strategy, the government and Danish Regions propose to renew the definition of the concept of 'personalised medicine'.

Definition of personalised medicine

Personalised medicine is an approach in the healthcare service in which early detection, prevention, diagnostics, treatment and follow-up must be more collaborative with the patient and thus adapted to the individual's unique profile and pathway. This individualised approach enables the use of health data and advanced technologies to create the most effective and targeted health promotion interventions.

Overview of the strategy initiatives

1

Patient centricity

The patient's perspectives, preferences and values must be more involved in research, the development of new treatments and individual treatment pathways. The patient is the expert on their own life, and their encounter with the healthcare service should reflect that.

Initiatives:

- Support the establishment of the Danish Knowledge Center for User Involvement
- Develop a patient engagement code of conduct for personalised medicine to ensure involvement and trust

2

Better treatment through individualised treatment pathways

We need to support more individualised and differentiated treatment pathways that are better adjusted to the individual. This results in more personalised and better treatment.

Initiatives:

- Support the development of pharmacogenetic analysis methods
- Explore opportunities and challenges for establishing a pharmacogenetic profile
- Reduce side effects through an individualised approach to drug selection

3

Better use of health data to realise the potential of research and innovation

By using data more systematically, we can tailor prevention, diagnose earlier and choose the treatment that best suits the individual. This means more precision, fewer side effects and faster results.

Initiatives:

- Identify opportunities to improve early detection through the use of health data
- Strengthen the Danish biobanks
- Mapping current practices and the value creation of citizen-generated data

4

Strengthening the ATMP area in Denmark

The ambition is for Denmark to be among the leading countries in research, development and utilisation of ATMPs. This will both benefit our patients and strengthen the life science industry in Denmark.

Initiatives:

- Support the development and deployment of ATMPs in academic environments

5

Faster and more accurate diagnosis and treatment with genomic data

We must improve the use of genetic data and whole genome sequencing in the Danish healthcare service. We will ensure a strong national infrastructure that enables genetic knowledge to be translated into tangible value for patients.

Initiatives:

- Variant and frequency databases - a more uniform and efficient knowledge of genetics
- Better patient care through effective use of genomic data

1. The patient at the center

The patient is the expert on their own life, which we take seriously. Therefore, patients' perspectives, preferences and values need to be incorporated more systematically in research, the development of new treatments and the individual treatment pathways. This also applies to relatives, who often play a crucial role in the patient's everyday life and the course of the disease.

When we take our starting point in the individual patient and actively incorporate their experiences, it adds more value to both treatment and research. This not only improves patient satisfaction, but also the clinical quality of care and efficient utilisation of resources in the overall healthcare service. Among other things, the patient is more compliant with treatment and better manages their disease.

We are already working with patient centricity today. However, there is potential to improve the patient perspective.

We often encounter complex ethical dilemmas, especially in personalised medicine. It can be about informed consent, about risk and efficacy, or about difficult choices when the treatment is new, experimental or uncertain. This is especially true for patients with rare diseases, who are in great need of our specialised healthcare service. It is crucial that patients have access to qualified counselling, guidance and support. They need to feel safe and well-informed, so they are equipped to engage in shared decision-making with healthcare professionals.

The patient perspective is not only essential in treatment, but also in research. Denmark is a pioneer in health research. We have one of the highest numbers of clinical trials per citizen in the world, making us an attractive country for both public and private organisations looking to develop treatments of the future. However, we need to do a better job of ensuring that more patients have the opportunity to participate in clinical trials and that the patients who participate are more reflective of the entire population.

At the same time, the Danes' high level of trust in the healthcare service is a strength we must safeguard. Danes generally trust that their health data is used in a sensible and ethically responsible way. That trust is not a given, which is why a sustained commitment to transparency, ethics and information is crucial. Trust is a prerequisite for future research and development.

With this strategy, the government and Danish Regions are taking the next step. We want to strengthen patient involvement in research, the development of new treatments and the individual treatment pathways. Patients must be at the centre of decisions shaping the future of healthcare.

Patient centricity supports these strategic indicators:

Putting the patient first

Spread personalised medicine across the healthcare service

Strengthen the framework for personalised medicine

A new path for Sofie

Sofie is 42 years old and has a rare autoimmune disease, and the treatments have either not worked or have given her serious side effects.

When she became a patient representative in a research project, it changed both the project and her view of the disease. Researchers wanted to create treatments targeting gene variants, but it wasn't until Sofie and others shared their experiences that they realised how the disease really affects patients' lives. Sofie spoke about fluctuating symptoms, a healthcare service that can be difficult to navigate and side effects that can be as harsh as the disease.

Her input changed the project. The clinical goals came to reflect quality of life, and the information material became easier to understand. Sofie's story shows that early patient involvement leads to research that works in real life.

The patient case is fictitious but could occur in clinical practice.

That is why we have …

Strengthened trust in health data with the life science strategy

With the life science strategy, the government has decided to establish a simple, transparent and digital option for Danes to register their opt-out from the use of their genetic data and biological material in research contexts. This will contribute to citizens' continued support and trust in the use of data in the healthcare service.

Patient involvement in everyday clinical practice

For the Regions, patient involvement is an integral part of the daily work. Personalised medicine is linked to the patient perspective, which is already integrated into clinical practice, planning and quality development in the healthcare service today. This applies to the actual encounter with the patient, but also at an organisational level, where there are various forms of user involvement panels and patient committees that actively establish partnerships and dialogue with patients and relatives in organising the healthcare service. Personalised medicine is part of this work and of the Regions' continued development of the patient perspective, spearheaded by units such as the Center for Shared Decision Making, the Center for Patient Involvement and DEFACTUM.

Choose Wisely

Danish Patients and the Medical Societies have created the Danish Choose Wisely organisation, which today is a strong professional partnership. Choose Wisely, funded by Danish Regions, focuses on identifying unnecessary examinations, treatments and procedures in the healthcare service that do not benefit patients and, in the worst case, can harm them. The organisation develops recommendations on what to avoid and proposes solutions to bring about necessary changes. Choose Wisely ensures that the healthcare service's resources are spent on what provides value for patients and is professionally relevant. Through equal collaboration between patients and professionals, specific recommendations are developed on which treatments and procedures should be avoided in the Danish healthcare service.

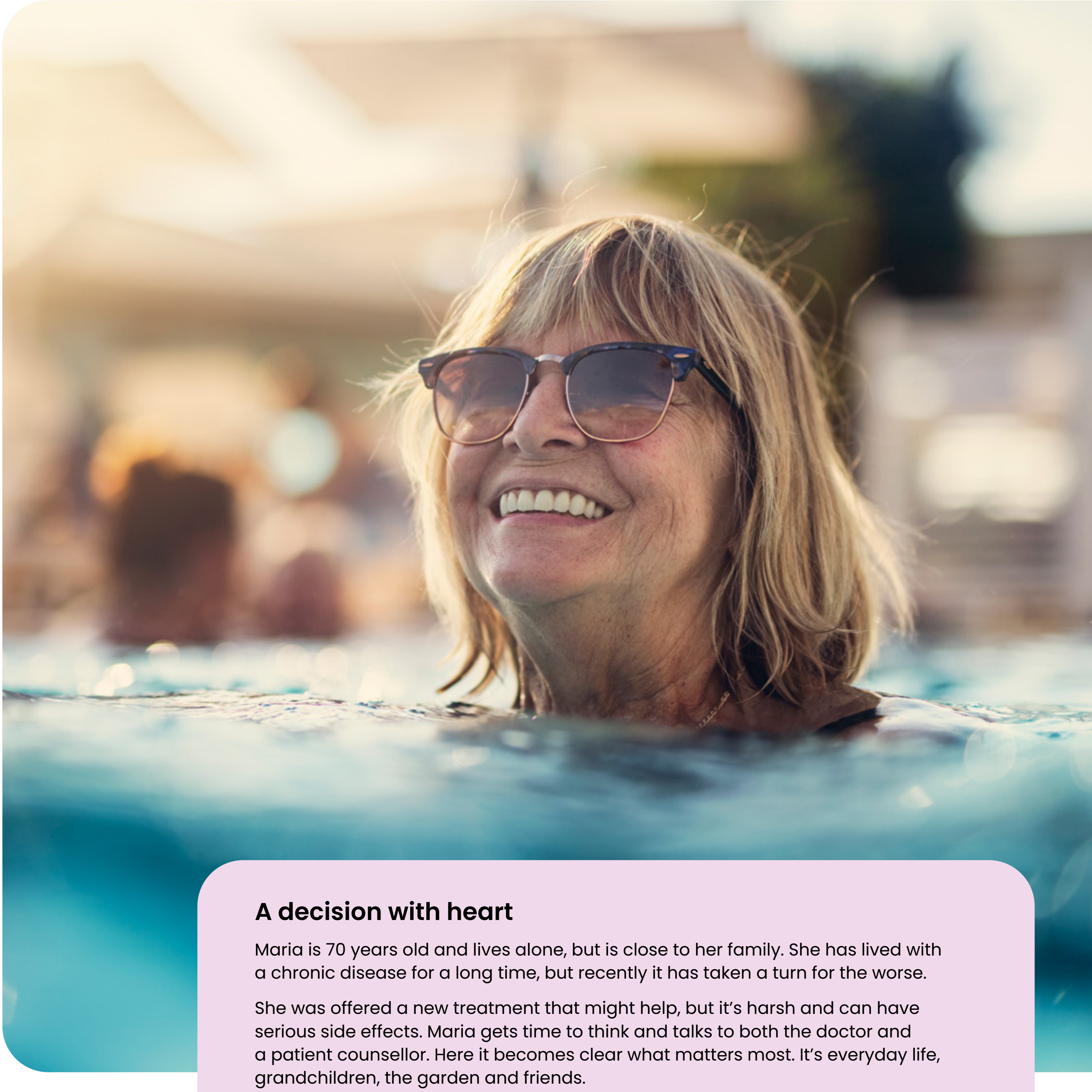
Now we want to …

Support the establishment of the Danish Knowledge Center for User Involvement

The government and Danish Regions support the establishment of the Danish Knowledge Center for User Involvement, which will strengthen user and patient involvement in personalised medicine. The importance of this has previously been addressed by the government in the latest life science strategy. The new Danish Knowledge Center for User Involvement will be anchored in Danish Patients, and a specific programme will be launched under the centre called "Programme for the patient perspective: Collaboration, ethics and trust." The programme will ensure that patients' knowledge and what is important to them becomes an integral part of personalised medicine. Among other things, an interdisciplinary counselling service will be launched within personalised medicine, where patients and relatives can receive support and advice as part of a shared decision-making process to choose the right treatment. The centre will be established in synergy and partnership with central, independent professional environments for user involvement, as well as already established centres in the Regions within user involvement, to ensure that it is in line with what has already been established regionally. The centre will also work closely with patients and relatives, professionals, universities, suppliers and authorities, among others.

Develop a patient engagement code of conduct for personalised medicine to ensure involvement and trust

The government and Danish Regions will further improve patient and user involvement in personalised medicine by developing a code of conduct for patient involvement in future developments in research, clinical trials, innovative solutions and new treatments and medicines. The code of conduct is intended to guide patient and user involvement in personalised medicine, including how to address specific dilemmas to ensure the transparency needed to maintain patient trust in personalised medicine research, treatment, and the healthcare service's use of health data. The code of conduct should be developed in collaboration between different perspectives and interests, including research interests, commercial interests, authorities, professionals and patients. The code of conduct is particularly relevant in areas with rapidly evolving data use, such as personalised medicine, artificial intelligence and life science.



A decision with heart

Maria is 70 years old and lives alone, but is close to her family. She has lived with a chronic disease for a long time, but recently it has taken a turn for the worse.

She was offered a new treatment that might help, but it's harsh and can have serious side effects. Maria gets time to think and talks to both the doctor and a patient counsellor. Here it becomes clear what matters most. It's everyday life, grandchildren, the garden and friends.

After consideration, she opts for a gentler treatment at home with home care. It doesn't promise miracles, but it does provide peace of mind and quality of life.

Maria didn't get the most advanced treatment, but the best for her, because she got to choose for herself.

The patient case is fictitious but could occur in clinical practice.

2. Better treatment through individualised treatment pathways

People are different, which is also true when it comes to how we respond to medication. Some experience side effects, while others feel nothing. And for some patients, certain medicines work, but not for others.

With personalised medicine, we can tailor the treatment to the individual patient to a much greater extent. This can mean faster initiation of the most effective treatment and possibly fewer side effects from treatments that don't have the desired effect.

The development is moving fast. New technologies, such as artificial intelligence, open new possibilities for more targeted treatment. By analysing large amounts of data, we can identify patterns that help us make more accurate diagnoses, predict the course of the disease and start the right treatment earlier in the pathway. For the patient, this means a greater quality of life and freedom. At the same time, it can free up resources in the healthcare service.

One of the new and rapidly developing technologies is pharmacogenetics - the study of how an individual's genes affect the body's response to medicine. This approach has the potential to better target treatment from the start and choose the medicine that best suits the individual. In the long run, this can help to faster find the most effective treatment with the least risk of side effects.

However, it requires that we dare to use these technologies and invest in making them part of everyday life in hospitals and clinics.

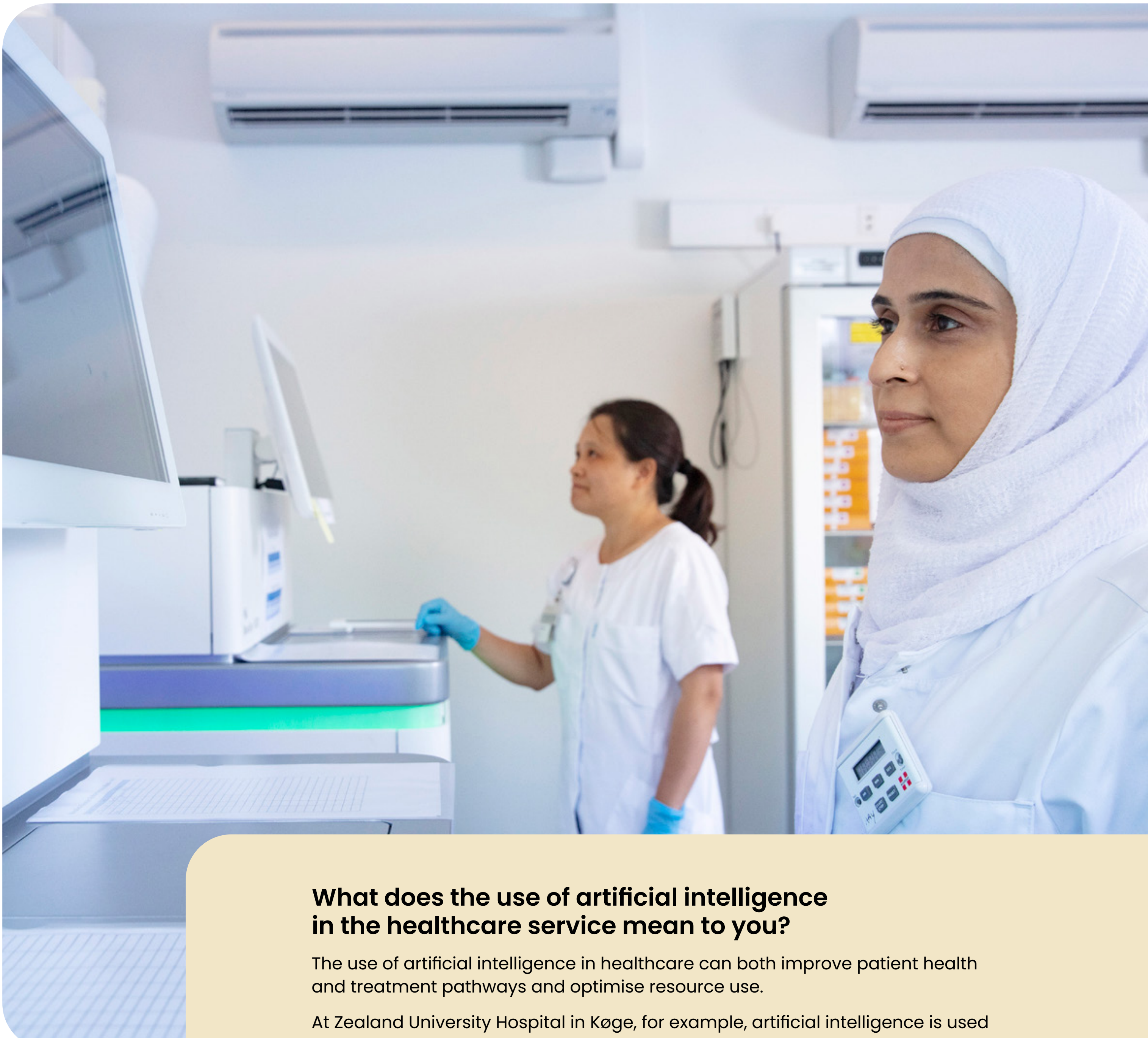
To unlock the potential of personalised medicine, the government and Danish Regions will strengthen efforts to develop individualised patient pathways tailored to each patient. We must seize the new opportunities and ensure that more people get the right treatment the first time.

Better treatment through individualised treatment pathways supports these strategic indicators:

Putting the patient first

Spread personalised medicine across the healthcare service

Using health data and artificial intelligence wisely



What does the use of artificial intelligence in the healthcare service mean to you?

The use of artificial intelligence in healthcare can both improve patient health and treatment pathways and optimise resource use.

At Zealand University Hospital in Køge, for example, artificial intelligence is used to analyse data from over 76,000 previous bowel cancer operations. Based on the analysis, patients are categorised into different risk groups according to their risk of complications after surgery. The most vulnerable patients are offered an intensive pre-surgery programme that may include physical exercise, lung exercises and dietary advice. The aim is to improve the patient's physical condition before surgery to reduce the risk of complications and promote a faster recovery.

The preliminary results are promising. Fewer readmissions were recorded, and among the first 75 patients, no vulnerable patients experienced severe complications after surgery, which 510 patients usually experience. For very vulnerable patients, hospitalisation time was cut in half.

That is why we have …

Investing in the deployment of artificial intelligence and new health technologies

With Cancer Plan V, the government focuses on improving patient treatment by investing in research and deploying artificial intelligence and new healthcare technologies. Funding has been allocated for research to gain new knowledge about the possibilities of using artificial intelligence in the development of personalised medicine, including, for example, improving early detection, precise diagnostics, tailored treatment and decision support.

The government has also set aside permanent funds to promote the spread of mature technology solutions, including artificial intelligence and other health technologies that can support personalised medicine.

Finally, the initiative should be seen in the context of the 2024 healthcare reform agreement, which allocates DKK 2 billion to innovation and digitalisation in the healthcare service from 2026 to 2035.

Research into the use of new technologies for individualised psychiatric treatment

New technologies can help create individualised treatment pathways for psychiatric patients. As part of its focus on improving psychiatry, the government has invested in new technologies to support the spread of personalised medicine in psychiatry. Therefore, as part of the psychiatry plan, funds have been allocated to support the VIRTU Research Group, which integrates advanced technology into psychiatric treatment to support personalised medicine. The use of virtual reality creates realistic treatment environments in which the patient's reactions can be observed, and treatment can be precisely customised to the individual.

Systematic patient involvement and differentiated cancer packages for the benefit of patients

With Cancer Plan V, the government will further develop the cancer packages, so they can take the individual patient's health, treatment options and wishes for the course of treatment into account to an even greater extent. The aim is to ensure that all cancer patients have their wishes and needs systematically clarified throughout the cancer pathway, and that there is an ongoing mutual matching of expectations and dialogue about the right cancer pathway for the individual patient, so that the patient's perspective takes centre stage.

Now we want to ...

Support the development of pharmacogenetic analysis methods

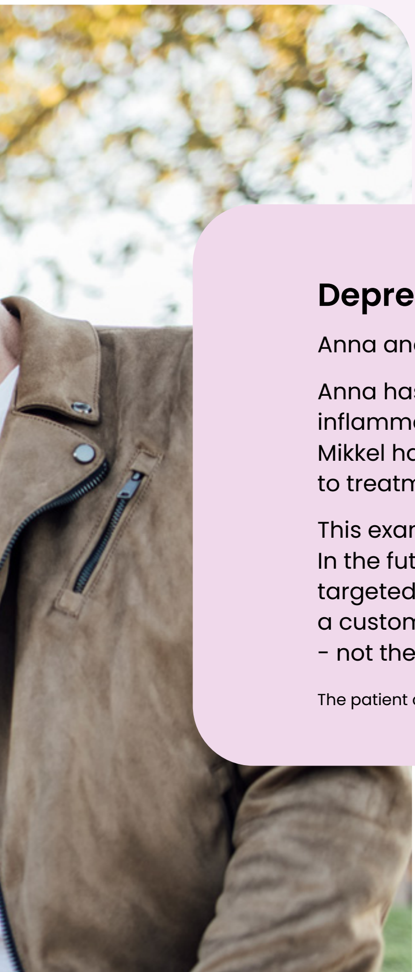
The government and Danish Regions will explore the possibility of improving patients' access to individualised drug treatment. Funds will therefore be allocated to develop and validate an analytical method to investigate tailored drug recommendations based on patients' genetics. By selecting and dosing medication based on a person's genetically determined ability to metabolise it, the risk of side effects and the need for repeated contact with the healthcare service are reduced.

Explore opportunities and challenges for establishing a pharmacogenetic profile

The Danish government and Danish Regions are allocating funds for a pilot project to explore the opportunities and challenges of introducing pharmacogenetic testing in Denmark, to tailor the dose of medication to the individual's genetics and thereby reduce unnecessary medication and side effects. This applies to antidepressants, for example, where the effect of the medicine does not materialise until up to six weeks after starting the medication, even though side effects are felt immediately. Patients may therefore have to live with side effects for some time while they wait for an effect that may not materialise.

Reducing side effects through an individualised approach to drug selection

The government and Danish Regions will investigate whether existing health data can be used to select the most effective treatment for the individual patient, taking into account their unique characteristics. This applies, for example, to the choice of medicine, where some patients experience a lack of efficacy or side effects that could have been avoided. As a result, they often must try several medications before finding the one that works best for them. In the pharmaceutical field, we already have a large amount of high-quality data that can support individualised treatments, which is why the government and Danish Regions are setting aside funds for a pilot project to help spread the individualised approach to future treatments. The pilot project is based on blood pressure medication.



Depression and precision psychiatry

Anna and Mikkel both have depression, but their pathways are very different.

Anna has a hereditary tendency towards severe depression and signs of inflammation. She has tried many treatments without finding the right one. Mikkel has no hereditary taint and no inflammation. He responds better to treatment, but also realises that standard methods don't always work.

This example shows that depression has many different levels of severity. In the future, treatment should be more personalised. Anna needs targeted help based on her biology and family history, while Mikkel needs a customised intervention to suit him. Treatment should be personalised - not the same for everyone.

The patient case is fictitious but could occur in clinical practice.

3. Better use of health data to realise the potential of research and innovation

Denmark has some of the world's most comprehensive healthcare data - from national registries, quality databases and biobanks to digital patient records dating back many years. This gives us a unique basis for understanding diseases, targeting treatment and intervening earlier in the patient's pathway.

Using Danish healthcare data can improve knowledge of the quality of the healthcare service and ensure Danish patients have access to the most effective treatments. What works, and what doesn't? What can be done better? Through health data, we can develop the healthcare sector and ensure that Danish patients continue to receive world-class treatment.

Today, health data is already actively used in encounters with the healthcare service. But we are not fully realising the potential.

By using data more systematically, we can better tailor prevention, diagnose earlier and choose the treatment that best suits the individual. This means more precision, fewer side effects and faster results.

At the same time, data provides a firm foundation for innovation and research across the healthcare sector. When we can connect knowledge across disease areas and patient groups, it opens new therapies and technologies. Furthermore, Denmark's strong digital infrastructure provides a solid foundation for realising the many opportunities in personalised medicine.

Early detection can make a difference for specific patient groups. When diseases are detected earlier, more people can avoid getting very sick and prolonged illnesses. And those who are already affected can get help before the disease becomes severe. However, early detection also raises many ethical questions. Fear of illness can affect the quality of life for some and create a false sense of security for others. Therefore, there is a need to learn more about this area.

At the same time, we need to strengthen the framework for the use of health data in research and development. Under clear ethical and legal conditions, health data should form the basis for new technologies and treatments, including the use of artificial intelligence and personalised medicine.

Better detection of invisible hereditary disease will save lives

Around 27,000 Danes suffer from familial hypercholesterolaemia (FH) - a hereditary and congenital disease that causes high blood cholesterol levels. If left untreated, there is an increased risk of heart disease and early death.

The disease is treatable if detected, but FH often causes few or no symptoms.

That is why the government and Danish Regions have set aside DKK 10 million from 2025 to 2028 to improve disease detection so that more people can receive treatment. Detection should be done through a more targeted and systematic use of health data from blood tests.

The Region of Southern Denmark and the Capital Region of Denmark already have good experience using blood test data to detect FH and refer patients to lipid clinics that can treat the disease. This needs to be rolled out to all regions as soon as possible.

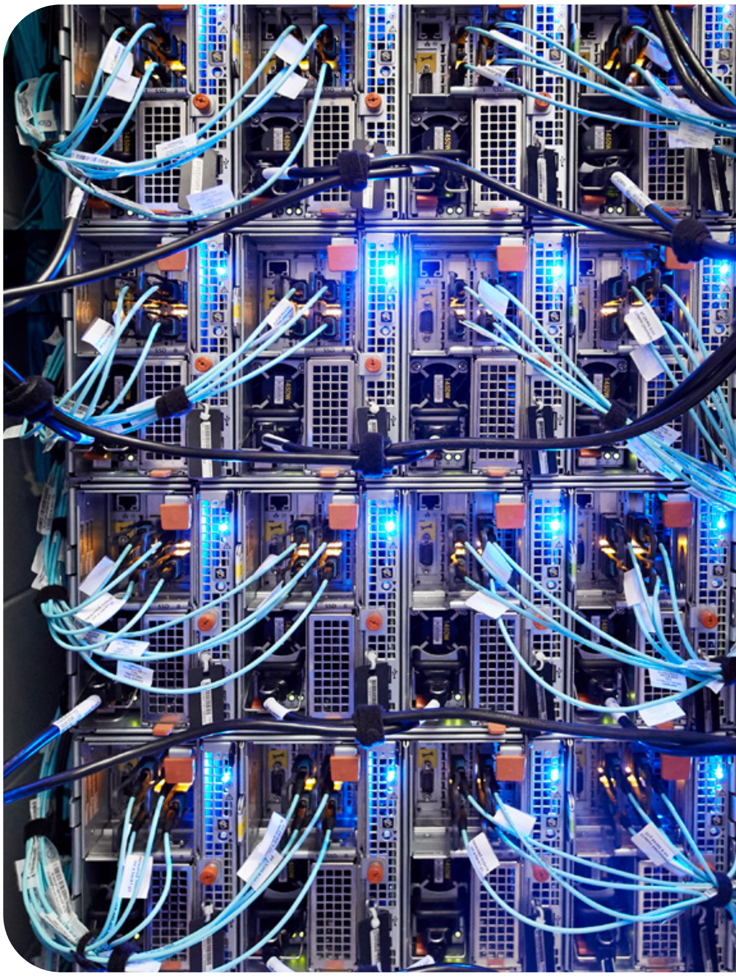
Because the disease is hereditary, family tracing is strengthened through improved and more easily accessible patient information, so more patients and their families are better informed about the disease and the options for testing and treatment.

The government has already taken important steps with legislative changes to create a more agile framework for the responsible use of health data. With the establishment of a single point of contact for accessing health data, data access will be simpler and smoother in the future. In addition, it enables advanced analyses across data sources, while maintaining high data security and complete transparency.

But we're not there yet. There are still legal barriers that hinder the free and secure use of data. To realise the full potential, we need a more coherent and efficient framework for collecting, sharing and using data, both in research and clinical practice.

In the future, we must also become better at using the data that citizens themselves create in their everyday lives, for example, through health apps such as activity trackers. Citizen-generated health data can provide a more nuanced picture of a patient's life and health, support preventive efforts and improve follow-up. It's an area with great potential, both for the individual and for the healthcare service as a whole.

With this strategy, the government and Danish Regions want to reinforce Denmark's position as a pioneer in health data, research and innovation. Health data must be utilised even more for the benefit of patients, research and the healthcare service as a whole.



Better use of health data to realise the potential of research and innovation in personalised medicine supports these indicators:

Free up resources and increase quality in the healthcare service

Using health data and artificial intelligence wisely

Strengthen Denmark's biobanks and health databases

Spread personalised medicine across the healthcare service

That is why we have ...

A vision for the better use of health data

The investments in the better use of health data should be seen in the context of the vision for its better use, founded in public-private collaboration and supported by the Novo Nordisk Foundation. The vision is based on the desire to use the large amounts of health data that already exist in the Danish healthcare service more efficiently and coherently for research and quality analyses. Of course, as we use more data in the future, we must contin ue to do so securely.

A single point of contact for secondary use of data is being established, giving researchers, authorities, companies, etc., a single point of access to health data in Denmark. At the same time, the application process for access to health data is unified across data controllers, ensuring faster and more uniform processing of applications. Finally, a new analytics platform will be established to enable advanced analyses across data sources.

This creates a coherent user journey from the researcher's initial identification of possible data sources to the application for access to data, to the approval of the application, and to the transfer of data into secure analysis environments.

The goal is to improve the quality of treatment and prevention, strengthen research and continue to ensure public trust through high data security and transparency.

A change has also been made to the Danish Health Act, which will eventually make it possible to use registry data directly in patient treatment as decision support.

The regional data support centres

The regional data support centres are a service function that, in particular, enables researchers to access advice, services and support for the use of health data through a single point of access. This can include help understanding and using health data for research purposes, including assistance with linking data across data sources, data processing and analysis, general project support and legal assistance. At regional data support centres, users will receive a warm welcome at the front door and be assisted safely and professionally, avoiding unnecessary time and resources spent obtaining data. Therefore, data support centres play a key role in providing advice, service and support for the use of healthcare data.

Bio and Genome Bank Denmark (RBGB)

RBGB is a nationwide, cross-regional infrastructure that contains more than 49 million biological materials, including blood samples from various biobanks. RBGB works to secure biological material for analysis and use in the assessment and treatment of individual citizens, and for research into new treatments and personalised medicine.

Now we want to …

Identify opportunities to improve early detection through the use of health data

The government and Danish Regions are allocating funds for an analysis to investigate the potential of early detection of chronic diseases using health data, for example, in relation to familial hypercholesterolaemia (FH). Among other things, the analysis will map the legal and ethical challenges in the area. The analysis is carried out with an eye on ongoing activities to better detect FH as described in the 2025 SSA agreement. The analysis is limited to general practice. At the same time, funds will be allocated to a pilot study to identify opportunities to improve early detection in the healthcare service. The pilot is evaluated based on impact, costs and barriers to implementation.

Strengthen the Danish biobanks

The Danish government and Danish Regions want to strengthen Danish biobanks. Biobanks in Denmark hold millions of samples of biological material, including blood samples from population surveys and patients with various diseases. Analysing biological material is crucial for personalised medicine. When samples are collected, recorded and structured uniformly, it becomes easier to link them with relevant health data and translate them into specific knowledge for both research and treatment. At the same time, a newly developed solution will enable citizens to gain insight into their own samples stored in biobanks. This helps to ensure knowledge, transparency and thus trust in the extensive research resources in biobanks. A strengthened biobank system is therefore a prerequisite for realising the potential of personalised medicine, and helping more patients receive the right treatment for each individual.

Mapping current practices and the value creation of citizen-generated data

The government and Danish Regions will allocate funds to investigate current practices for using data from citizens' own devices, such as health apps as activity trackers, and how these can create value in specific disease areas. In addition, a follow-up pilot project is planned that, in both the short and long term, can promote the individualised approach to treatment in Denmark through the use of citizen-generated data.

A future with the use of health apps

Jesper lives healthy and feels healthy. However, when his father had a blood clot, doctors discovered that he had familial hypercholesterolaemia (FH) - a hereditary disease with high cholesterol and an increased risk of heart disease, often without symptoms.

Jesper is offered a genetic test, and it turns out that he has inherited the same genetic defect. Although he doesn't feel anything, he is immediately recommended cholesterol-lowering treatment to prevent blood clots. Through an app, Jesper gets help to customise his diet and medication and is supported in parts of his treatment pathway via the app. He also had his children tested, and his daughter has inherited the disease. Now she too can start early treatment. Early knowledge and preventive action can protect the whole family from a serious illness.

The patient case is fictitious but could occur in clinical practice.

4. Strengthening the ATMP area in Denmark

Advanced Therapy Medicinal Products (ATMPs) are a new breakthrough treatment that could cure diseases previously considered incurable, for example, by altering the patient's genes. ATMPs therefore have enormous potential to improve the treatment of patients with severe and rare diseases. Often, where traditional treatments fall short.

Denmark is well-positioned to lead the way. We have a strong life science industry and academically strong research environments in hospitals and universities.

The ambition is for Denmark to be among the leading countries in researching, developing and utilising ATMPs, thereby benefiting our patients and strengthening the life science industry in Denmark.

The government has already taken an important step. As part of the life science strategy, the government has established ATMP Denmark, an overall effort to improve the development and use of ATMPs in the Danish healthcare system.

ATMP Denmark is a national collaborative structure involving the healthcare service, research and industry. The focus is on identifying challenges and finding solutions, especially regarding the regulatory aspects of the process from research and development to the deployment of ATMPs. In addition, work is underway to collect and utilise real-world data on the efficacy of ATMPs in connection with approval.

The field of ATMPs is characterised by both great potential and complexity. Working with ATMPs is characterised by a complex regulatory framework that many clinicians and researchers find difficult to navigate. Pricing and uncertainty about long-term effects can also delay development. Today, the Danish Medicines Council and Amgros can enter into alternative price agreements with pharmaceutical companies. Furthermore, the Danish Medicines Council can make conditional recommendations provided that a follow-up data collection is carried out after the medicine is put into use to gain more knowledge about its effectiveness. Amgros has today entered into two effect-based agreements on ATMPs, but we need to improve our follow-up. Therefore, there is a need to develop models for collecting real-world evidence that can be used to follow up on the impact of ATMPs. The collection needs to be more systematic and automated.

Under the strategy, the government and the Danish Regions aim to strengthen ATMP Denmark. We want to make it attractive for companies to collaborate with Danish hospitals and universities, and support the development of ATMP treatments in academic environments. We will take these ambitions into the European work so that Denmark can be a pioneer in the development of ATMPs on the international stage for the benefit of patients, research and the future healthcare service.

What are ATMPs?

Advanced Therapy Medicinal Products (ATMPs) are a collective term for gene therapies, cell therapies and tissue engineering technologies. They consist of biological material that has been modified to replace a missing function or repair a disease-causing dysfunction in the patient. Often, these are one-off treatments that can offer better and potentially curative treatment for severe and rare diseases for which there has been no effective treatment in the past or where conventional treatment methods require continuous therapy.

Hemgenix: A new beginning

A patient who has lived for many years with severe haemophilia B, a condition that causes frequent bleeding and requires weekly infusions of preventative medication, has been given a second chance with the gene therapy Hemgenix.

The treatment has recently been recommended by the Danish Medicines Council and exemplifies the latest developments in ATMPs. Hemgenix works by introducing genetic code into the body, which causes it to produce the necessary coagulation factor IX, allowing blood to clot. This means the patient only requires a single dose, eliminating the need for weekly treatments, which is currently a significant burden.

Gene therapy has allowed patients to live a life with less bleeding, greater independence and a renewed chance at a more normal everyday life. This innovative treatment shows how advanced gene therapy can be a truly curative option in some cases.

Strengthening the ATMP area in Denmark supports these strategic indicators:

Strengthen the framework for personalised medicine research

Spread personalised medicine across the healthcare service

Making Denmark a leader in advanced therapies

That is why we have …

Better use of data for follow-up

With Cancer Plan V, the government has allocated funds to establish a collaboration between relevant public and private actors under the leadership of the Danish Medicines Council to clarify how health data (real-world evidence) can be collected and analysed more systematically to assess the effects of new and advanced cancer drugs after they are introduced. This will improve the Danish Medicines Council's options to make conditional recommendations for new cancer medicines in the future, so patients can get quick access to potentially better treatment.

The first ATMPs are already in use

The first ATMPs are already being used in the healthcare service. The Medicines Council has recommended nine ATMPs for 12 patient groups, corresponding to three of the four ATMPs assessed so far. Denmark is among the Nordic countries where most new ATMPs are recommended.

Now we want to …

Support the development and deployment of ATMPs in a public-private collaboration

The government and Danish Regions will improve ATMP Denmark's efforts by allocating additional funds to establish a coordination function that will serve as a single point of access for clinicians, researchers and companies to receive guidance, help establish collaborations on clinical trials, and support networks and knowledge sharing. The focus should be on both commercial ATMPs developed by companies and academic ATMPs developed by hospitals and universities.

Moreover, the government and Danish Regions will launch initiatives to support the development and deployment of ATMPs in academic environments at hospitals and universities, including:

- Creating a guide for developing academic ATMPs in hospitals and universities.
- Developing standards for clinical trial development and applying for funding for national research projects to facilitate and streamline collaboration across the country.
- Address barriers for clinicians in developing and deploying academic ATMPs, including the procurement of regulatory advice and the purchase of licences for the production of ATMPs.
- Ensure a clear and transparent framework for a public-private collaboration.

5. Faster and more accurate diagnosis and treatment with genomic data

Since the human genome was mapped in 2003, genetic data has been a cornerstone in the development of personalised medicine. Genome data contains the genetic code that shapes how our bodies function. It affects how we respond to diseases and treatments.

New technology now allows us to understand each individual patient's genetic profile, enabling us to target prevention, diagnosis, and treatment much more precisely.

With previous personalised medicine strategies in collaboration with Danish Regions and the Novo Nordisk Foundation, the government has already taken crucial steps with the establishment of the Danish National Genome Center in 2019 to develop a secure and strong national infrastructure for personalised medicine and the national implementation of whole genome sequencing in clinical practice. Currently, over 43,000 patients have undergone whole genome sequencing, which in many cases can result in more precise and targeted treatment. This has put Denmark on the world map for genetic testing, which we are proud of. However, we must continue to develop in this area and support more patients' access to genetic testing.

Today, healthcare organisations use international databases when mapping patients' genomes. But there is a need for a Danish database that accounts for Danish conditions, which will make it faster and more accurate to interpret genetic data, for example, by recognising inherited gene changes specific to Danish families. This way, patients across the country can receive more consistent and effective treatment.

With this strategy, the government and Danish Regions want to improve the use of genetic data and whole genome sequencing in the Danish healthcare service. We will ensure a robust national infrastructure that enables the translation of genetic knowledge into tangible value for patients.

Whole genome sequencing

Whole genome sequencing is a method of mapping a person's entire genome to identify genetic variations. It provides a detailed picture of how diseases occur and how treatments can be targeted to the individual. The method is central to personalised medicine and paves the way for more precise and effective treatment.

Faster and more accurate diagnosis and treatment with genomic data support these strategic indicators:

Free up resources and increase quality in the healthcare service

Spread personalised medicine across the healthcare service

Strengthen Denmark's biobanks and health databases

That is why we have …

Better use of health data for personalised cancer treatment

Together with the Danish Healthcare Quality Institute (DHQI), the government will establish a national clinical database for personalised cancer medicine. This will ensure that vital knowledge about cancer treatments is systematically collected and utilised to benefit patients. A lot of data that could improve cancer treatment is currently unavailable to healthcare professionals and researchers. For example, data on how cancer drugs work more or less effectively for patients, depending on the patient's genetics or the cancer.

By recording and analysing this data, we can better understand which treatments work best for which patients, leading to more targeted, effective and gentle cancer treatments. At the same time, the database will improve research and quality development in the healthcare service, enabling new treatments to be assessed and implemented faster. For patients, this means that new potentially life-prolonging treatments can be introduced more quickly, while quality and safety are continuously evaluated and improved.

Now we want to …

Variant and frequency databases - a more uniform and efficient knowledge of genetics

To enable more citizens to benefit from genetic analyses, the government and Danish Regions will gather data in one place in a national variant and frequency database. Here you can quickly see if a gene variant has been seen before and how often it occurs in the population. This makes it easier to assess whether a gene alteration may impact a disease, improving both diagnosis and treatment. By gathering data nationally, we achieve a uniform, efficient solution, so patients in Denmark can receive a faster, more accurate diagnosis.

Better patient care through effective use of genomic data

Today, genomic data is stored in multiple locations because retrieving it from the national database is cumbersome and slow. Therefore, unnecessary resources are spent duplicating the same data. The Danish government and Danish Regions want to make it easier and faster to use the national genome database. Together with the regions and researchers, the database will be improved and further developed to make it easier for users to access and work with the data locally. This means that the healthcare service can save money on storage, ensure continued high security, and, at the same time, get more out of genomic data for better prevention, treatment, and follow-up.

Genomic analysis got Karina back on her feet

For several years, Karina’s life was characterised by pain and repeated fungal infections on her feet. Treatment only helped briefly, and the symptoms always returned, and her frustration grew.

A genomic analysis eventually revealed a congenital genetic defect and finally provided her with an explanation. With the diagnosis came new possibilities: a targeted, preventive treatment that addressed the root cause of the infections. Today, Karina is free from the pain and infections that used to restrict her. There is no cure for the disease, but she has received a treatment that is making a clear difference. For Karina, the genetic analysis meant not just a diagnosis, but a life without constant inconvenience.

Finances

The cost of initiatives for the personalised medicine strategy 2025-2027

	DKK million, 2025-PL	2025	2026	2027	Total
	Total	**30.0**	**30.0**	**30.0**	**90.0**
1.	**Patient centricity**	**12.2**	**0.0**	**0.0**	**12.2**
1.1	Support the establishment of the Danish Knowledge Center for User Involvement, including developing a code of conduct for patient involvement in personalised medicine to ensure involvement and trust	12.2	0.0	0.0	12.2
2.	**Better treatment through individualised treatment pathways**	**3.1**	**8.9**	**8.9**	**20.9**
2.1	Support the development of pharmacogenetic analysis methods	2.9	2.9	2.9	8.7
2.2	Explore opportunities and challenges for establishing a pharmacogenetic profile	0.1	2.4	3.0	5.5
2.3	Reducing side effects through an individualised approach to drug selection	0.1	3.6	3.0	6.7
3.	**Better use of health data to realise the potential of research and innovation**	**4.5**	**11.4**	**9.4**	**25.3**
3.1	Identify opportunities to improve early detection using health data	0.0	2.0	0.0	2.0
3.2	Strengthen Danish biobanks	4.5	7.9	7.9	20.3
3.3	Mapping current practices and the value of citizen-generated data	0.0	1.5	1.5	3.0
4.	**Strengthening the ATMP area in Denmark**	**4.8**	**2.1**	**3.1**	**10.0**
4.1	Improve the coordination function at ATMP Denmark	1.0	1.0	1.0	3.0
4.2	Developing a guide for developing academic ATMPs	1.3	0.1	0.1	1.5
4.3	Developing standards for clinical trial development and applying for funding for national research projects	0.5	0.0	0.0	0.5
4.4	Removing barriers for clinicians	2.0	1.0	2.0	5.0
5.	**Faster and more accurate diagnosis and treatment with genomic data**	**5.4**	**7.6**	**8.6**	**21.6**
5.1	Variant and frequency databases - a more uniform and efficient knowledge of genetics	3.6	6.6	6.6	16.8
5.2	Support and develop the infrastructure for more efficient use of genome data	1.8	1.0	2.0	4.8

Personalised medicine strategy
2025 - 2027

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