# Genomic Medicine Sweden

## Strategic Plan 2021–2030

# Summary

**Precision medicine is making inroads into healthcare across the world**
Precision medicine involves taking a more personalised approach to healthcare in which the individual patient can be more effectively diagnosed and treated with a reduced risk of short and long-term side-effects. This progress has largely been made possible by technological advances in gene sequencing and the approval of entirely new forms of treatment. Swedish healthcare is now able to sequence a patient's entire genome in only a few days.

**Mobilising Sweden's combined resources for the implementation and development of precision medicine**
Genomic Medicine Sweden (GMS) is a national collaboration aimed at ensuring that patients in Sweden have equal access to cost-effective genetic analysis to facilitate improved diagnostics and thereby more personalised care, treatment and prevention. GMS is led by Sweden's seven regional health authorities with university hospitals together with the seven universities with medical faculties. The collaboration also includes the fourteen remaining Swedish regional authorities, the private sector, patient organisations and SciLifeLab (the Swedish national research infrastructure for life science). At the same time as supporting the implementation of precision medicine in healthcare, GMS also strengthens the ability of Swedish research and innovation to develop tomorrow's diagnostics and treatments. Ultimately, this is a matter of improving public health and strengthening the position of patients and their ability to contribute to their own care and treatment.

> Equal access to genetic analysis for improved diagnostics and more personalised care, treatment and prevention.

**A unique collaboration on a common data platform**
GMS will contribute to the digitalisation of healthcare by laying the foundations for an infrastructure for the secure sharing of data between Swedish regional health authorities and with academia and the private sector. A common platform for genomics data is being built as a national, scalable system that will be transferable to other areas and for the benefit of the entire life science ecosystem, thereby strengthening research, development and innovation. This data platform will be designed to be able to utilise healthcare data using powerful AI-based analytical tools.

**A prioritised investment as part of Sweden's National Strategy for Life Sciences**
GMS is also one of the initiatives that will play a vital role in achieving Sweden's stated ambition of being a leading life sciences nation. GMS's strategic plan for the coming decade addresses several of the objectives of Sweden's National Strategy for Life Sciences. Above all, GMS has identified five overarching goals which it will work towards in order to realise the Government's objective of making Sweden a pioneer in the implementation of precision medicine in healthcare.

GMS has identified a number of key issues that are essential to resolve if we are to achieve a successful and equal implementation of precision medicine in Swedish healthcare. Among these key issues are coherent national coordination and management, coordinated implementation in healthcare and access to national clinical studies.

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GMS, which has been operating in project form since 2018, has built a strong foundation for the implementation of precision medicine in Sweden by bringing together key stakeholders. This document describes how GMS plans to continue the implementation of precision medicine in the period from 2021 to 2030.

> The Swedish Government's goal: Sweden shall be a pioneer in the implementation of precision medicine in healthcare.

# GMS's overarching objectives for a long-term investment

1. **Implementation of broad gene sequencing in healthcare to improve diagnostics and equity in care for all patients.** The implementation of equitable, resource-efficient, gene sequencing-based diagnostics in healthcare services to facilitate personalised care and treatment, i.e., precision medicine of the highest quality.

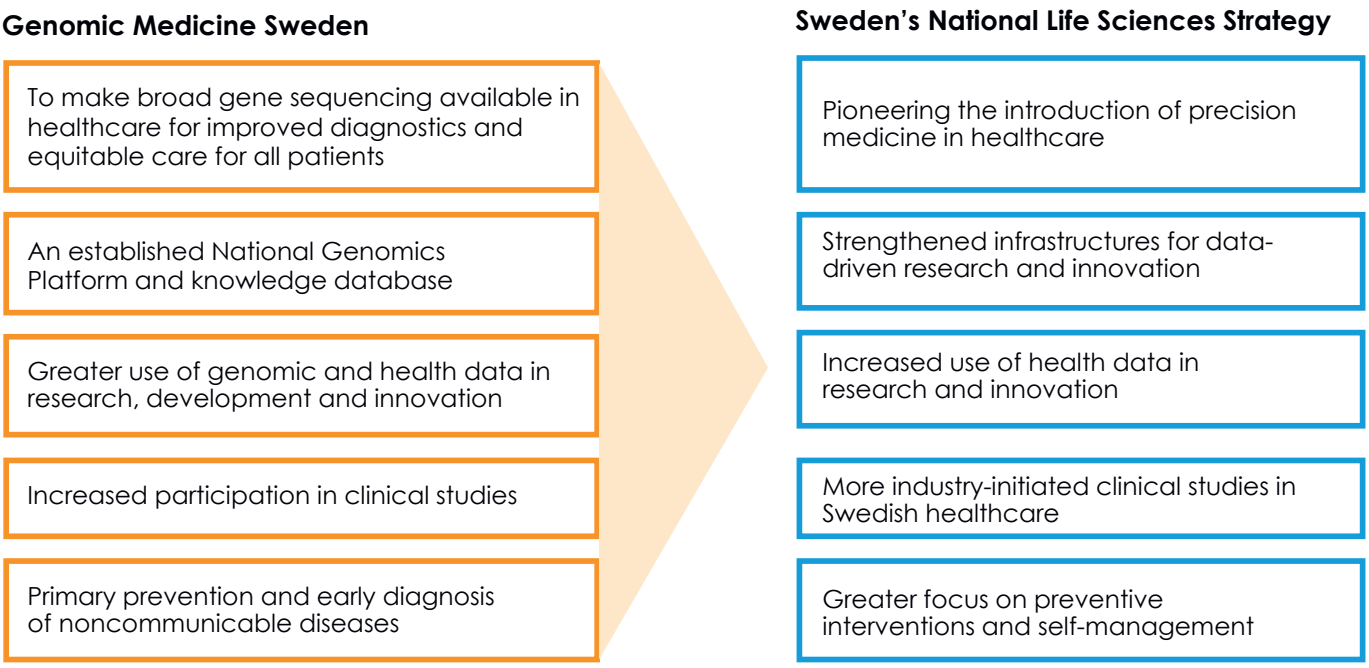
2. **An established National Genomics Platform and knowledge database.** A common National Genomics Platform and knowledge database containing molecular data linked to healthcare data, and intelligent digital decision support that facilitates patient-centred care, research and innovation.

3. **Greater use of genomic and health data in research, development and innovation.** The National Genomics Platform and knowledge database delivers top-quality molecular data that is used by both academia and industry so that, together with the healthcare sector, they can contribute to improved patient care.

4. **Increased participation in clinical studies.** Work to ensure that more clinical studies are conducted and that patients are offered greater opportunities to participate in clinical studies, as the implementation of broad diagnostic sequencing makes it possible to recruit directly via healthcare providers. This infrastructure permits the rapid introduction of diagnostics and treatment results into clinical use.

5. **Increased focus on primary prevention and early diagnosis of noncommunicable diseases.** Cost-effective sequencing is used for early diagnosis, to personalise treatment or completely avoid various noncommunicable diseases – i.e., precision health – and to increase preparedness for quickly dealing with public health threats such as outbreaks of new infectious diseases.

## GMS's overarching objectives linked to the goals of Sweden's National Life Sciences Strategy



# Key issues for the implementation of precision medicine in Swedish healthcare

Based on an analysis of ongoing GMS investments and other national initiatives, there is a need for a coherent strategy and well-balanced choices specifically focused on Swedish conditions for the implementation of precision medicine in Sweden. GMS has therefore identified seven key issues that need to be resolved in order to ensure that Swedish patients have access to current and future precision medicine. The key issues therefore stake out the strategic priorities for precision medicine and GMS in the period until 2030. If we fail to address these key issues, the risk is high that Sweden will fall behind comparable countries when it comes to providing access to the personalised prevention, diagnostics, treatment and monitoring made possible by precision medicine.

**Stronger together: national coordination and management**
The implementation of the GMS initiative and precision medicine requires robust national coordination and management in accordance with the National Life Sciences Strategy's objectives of national coordination and partnership with regions. Coordination will provide economic benefits and better utilisation of the competences spread out across the country. Other important areas of national coordination include health economic analyses and highlighting the ethical and legal aspects of data sharing.

**Digitalisation: a National Genomics Platform for the secure use of genomic data**
A national IT infrastructure for storing genomic and associated data, in the form of a National Genomics Platform for the healthcare sector, will provide obvious benefits given that individual investments within the seven university hospital regions would prove significantly more expensive. This platform provides greater opportunities for coordination with biobanks, Swedish National Quality Registries and electronic healthcare records. A common, scalable infrastructure also provides data interoperability, thus opening the way for new medical innovations and research breakthroughs. The National Genomics Platform will contribute to the digitalisation of Swedish healthcare through increased opportunities to securely use healthcare data.

**Knowledge management: technological development and national implementation**
Technological development in the field of precision medicine is advancing rapidly. New technologies will be evaluated on an ongoing basis within GMS and in collaboration with SciLifeLab. GMS will thereby ensure that patients in Sweden are provided with access to precision medicine in an evidence-based and expeditious manner.

The GMS initiative will harmonise with Sweden's new national system for knowledge management in healthcare, in particular with regard to implementing genetic analyses at Sweden's seven regional Genomic Medicine Centres (GMCs). GMS will work actively with clinical programme groups within the focus areas rare diseases, cancer, infectious diseases and complex diseases.

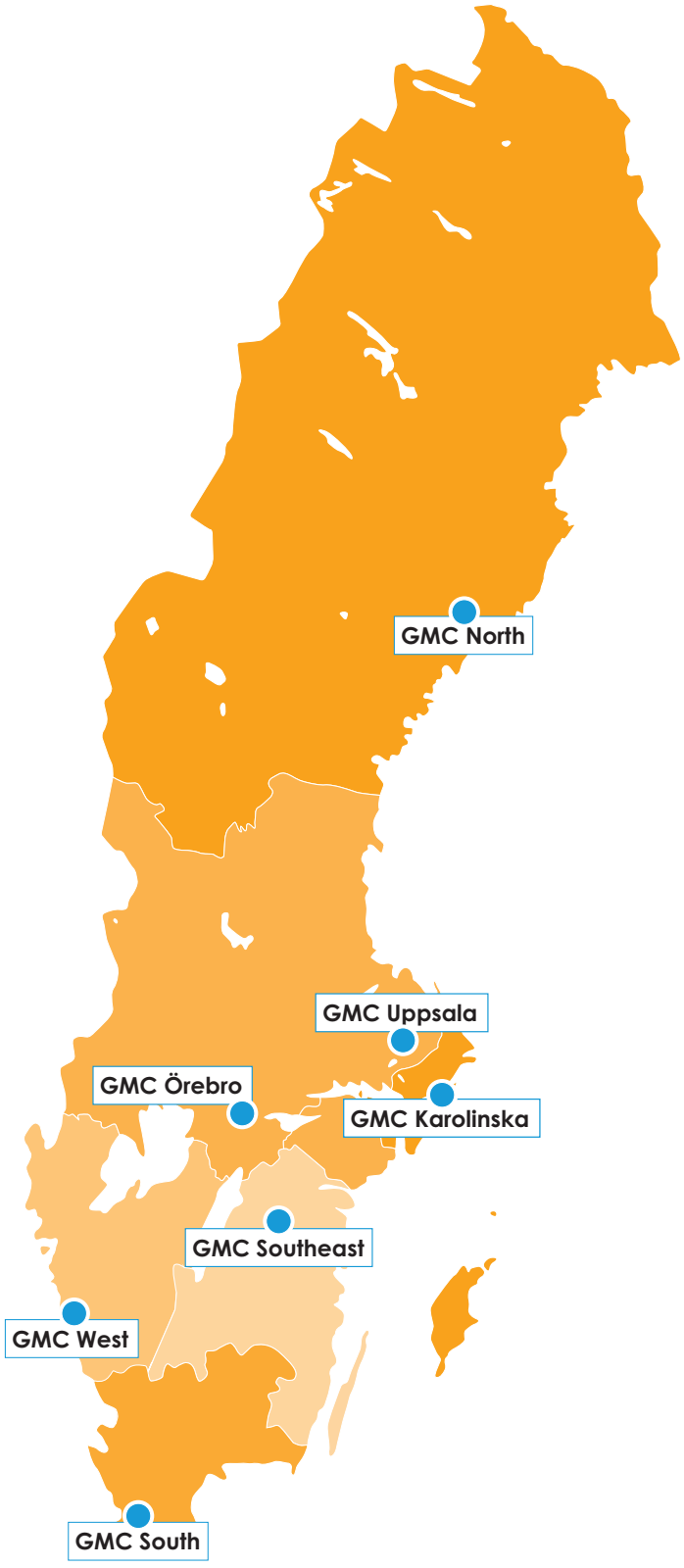
**Increased access to national clinical studies**
In order to ensure that Swedish patients have access to the best treatment options, GMS will actively stimulate and facilitate academic and industry-initiated clinical studies within its focus areas at national level. Here, the generation and dissemination of genetic data will be crucial to offering patients opportunities to be part of a clinical study.

**Strong patient influence: collaboration with patient organisations**
Understanding patients' needs and experiences is central to the development and implementation of broad genetic analysis in healthcare to improve diagnosis, treatment and monitoring. GMS actively collaborates with patient organisations. Two of these, Rare Diseases Sweden and the Swedish Network Against Cancer, are represented on GMS's steering committee.

**Training and skills development for healthcare professionals**
The long-term, stable implementation of precision medicine in Swedish healthcare will demand extensive professional development and basic and advanced courses for various categories of staff in both laboratory and clinical medicine. It is GMS's intention to contribute to this in collaboration with regional health authorities and institutes of higher education to ensure that requisite knowledge is made available.

**Partnerships with industry for new advanced diagnostics and treatments**
Long-term partnerships with industry will be key to the successful development of precision medicine. The National Genomics Platform is a critical prerequisite for the secure use of digital health and genomic data, so that new advanced diagnostics and treatments can be developed in collaboration between healthcare, academia and industry.

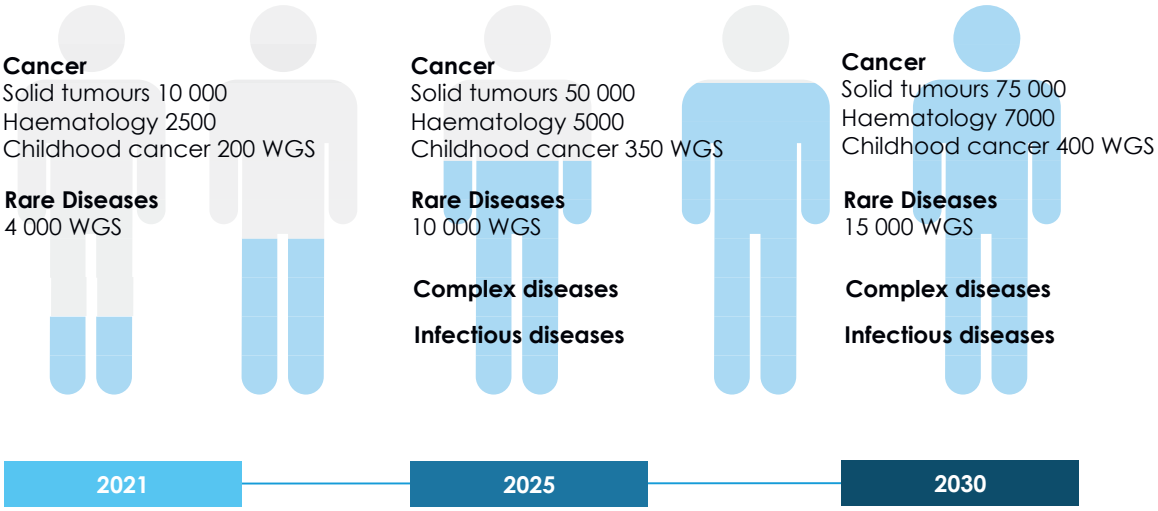
**The seven regional Genomic Medicine Centres (GMCs) established in the regions with university hospitals**



# A 10-year plan for GMS

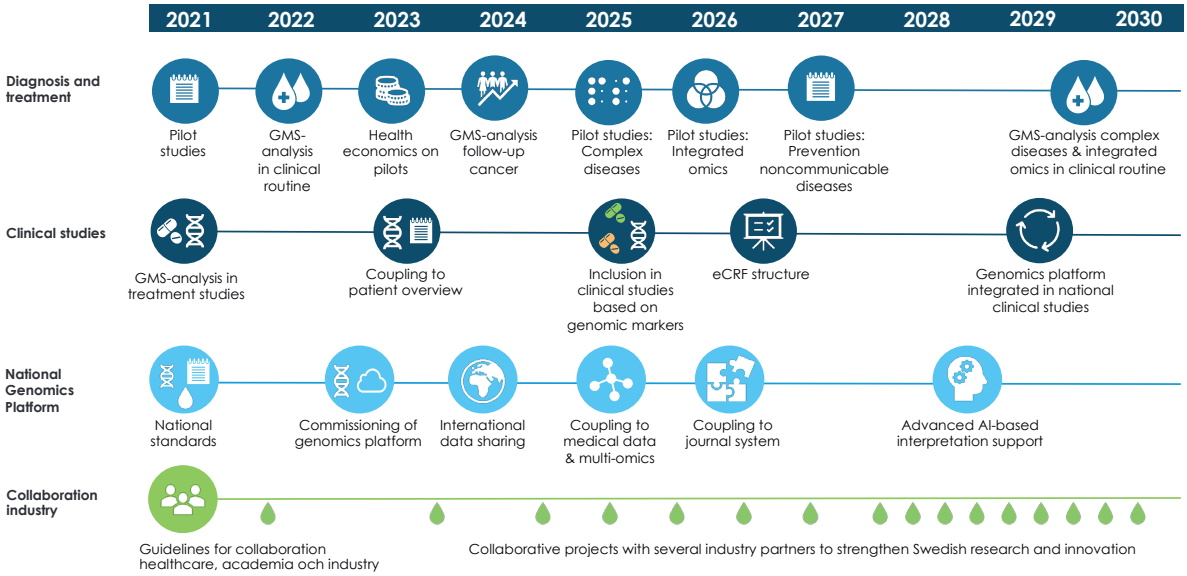
GMS's goal is to ensure that broad gene sequencing, such as broad gene panels and whole-genome sequencing, is routinely used within healthcare to improve diagnostics for patients with rare diseases, cancer, infectious diseases and complex diseases - all in the interests of providing improved monitoring, personalised care and treatment of patients. Broad gene sequencing is expected to replace many of the analytical tools in use today, providing more detailed information on which to base treatment decisions on. The number of samples analysed is expected to increase over time, with over 800,000 samples analysed in healthcare over a 10-year period.

## Sample volume per year during the period 2021–2030




Gene panels will be used for the analysis of solid tumours and haematologic malignancies prior to treatment decisions, with follow-up blood tests to monitor cancer development via cell-free circulating tumour DNA. Whole-genome sequencing (WGS) will be performed for rare diseases, childhood cancer, and, to a certain extent, haematology.

## GMS milestones 2021–2030




In order to fulfil the aims of the GMS initiative in both the short and long-term, a number of deliverables and milestones have been formulated based on the seven key issues and five overarching objectives defined by GMS. A more detailed project plan is available in Swedish at www.genomicmedicine.se

# Costs associated with implementing precision medicine

**Healthcare providers are already using gene-based diagnostics**
Healthcare providers are already funding diagnostics based on gene sequencing. Partly through co-financing of the ongoing GMS initiative but mainly through the funding of existing gene sequencing-based diagnostics. During 2019, the cost of gene sequencing-based diagnostics amounted to just over SEK 200 million. During 2019, samples were also sent abroad at a cost of approximately SEK 85 million. So, Swedish healthcare is currently paying for gene-based diagnostics to a cost of almost SEK 300 million.

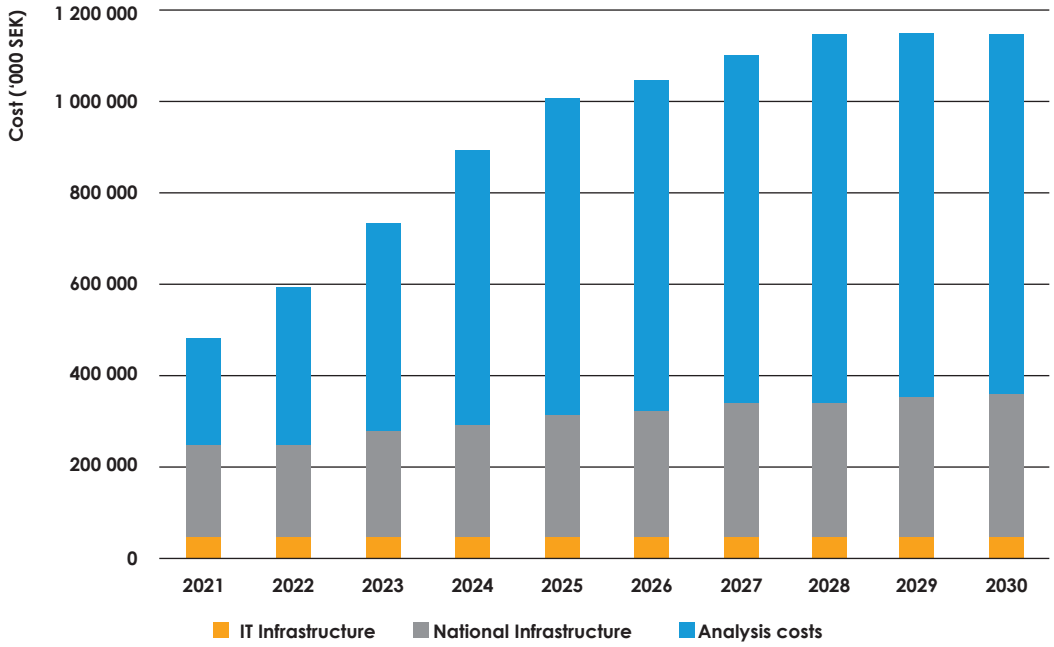
> Today, Swedish healthcare is paying for gene-based diagnostics at a cost of almost SEK 300 million annually

The cost of meeting the increasing demand for gene sequencing-based diagnostics is expected to rise sharply between 2021 and 2030 (SEK 790 million), largely due to an increase in the volume of samples and more analyses per patient.

**Implementing precision medicine**
A national investment makes it possible to share development costs and cost-effectively implement new diagnostics nationwide. The estimated cost over the coming 10 years is based on the key issues presented here and on the deliverables in the project plan. In addition to the costs of analysis, it is estimated that the cost for implementation of precision medicine in 2021 will be approximately SEK 200 million for the common national infrastructure plus approximately SEK 50 million for the common IT infrastructure. It is estimated that over the next decade annual costs will increase to approximately SEK 300 million for the national infrastructure and approximately SEK 60 million for the IT infrastructure.

The proposed budget is calculated based on the premise of Sweden achieving an adequate level in the field of precision medicine; further funds will need to be allocated in order to achieve the goal of being a world leader in the field.

## Budget overview 2021–2030




Costs for IT infrastructure and national infrastructure are divided into costs arising from the key issues presented above and costs associated with analysis.

> While the implementation of broad genetic analysis within Swedish healthcare will provide enormous benefits for patients, it will also entail significant costs.

**Shared regional and state responsibility**

While the implementation of precision medicine will provide enormous benefits for patients, it will also entail significant costs. It is clear that no single party is in a position to pay for this investment in its entirety. It will therefore be necessary to develop a cost-sharing model. Regional health authorities are facing significant economic challenges and are in no position to bear the full cost of developing and implementing gene sequencing-based analysis.

The social benefits accruing from patients living longer, being able to continue to work while undergoing treatment and/or return to work more quickly will have a significant impact on the social insurance system. It is therefore important that the state steps in as one of the principal funder of any investment in precision medicine. If precision medicine is to be a success, it is crucial that the scientific community and the healthcare sector work closely together to build the national infrastructure as described by GMS, another strong argument for the division of costs between the state and regions.

> At present, no single party is in a position to pay for the cost of implementation in its entirety.

A cost-sharing model must be the subject of further discussion between representatives of central government and regional authorities and a future partnership is envisioned.

# Long-term investment in precision medicine in the Nordic region, Europe and worldwide

Many countries are mobilising to implement precision medicine at national level. These investments have been justified by benefits to patients and to varying degrees by their value to clinical research and the business sector. The types of analysis encompassed vary. Several investments, such as those in Denmark and the United Kingdom, are focused on whole-genome sequencing analysis, while the objective of GMS is to develop all of the tools required for high-quality precision medicine, including targeted analyses such as gene panels.

## International experiences of precision medicine

**Denmark**
In the Nordic region, Denmark has established the Danish National Genome Center under the Danish Ministry of Health, which has received significant funding from the Novo Nordisk Foundation and the Danish Government. The budget for this investment is approximately SEK 1.4 billion (2019–2023).

**United Kingdom**
At a European level, the United Kingdom was the first country to commit a significant investment (approx. SEK 4.9 billion for the period 2013–2018) in precision medicine through the establishment of Genomics England in 2013. Having achieved the initial objective of sequencing 100,000 genomes from patients with rare diseases, as well as patients with cancer by the end of 2018, the UK Government now plans to sequence 5 million genomes over the next five years.

**France**
France is investing approximately SEK 7 billion until 2025 in building a national infrastructure for rare diseases and cancer.

**Australia**
At a global level, Australian Genomics is the latest example of a long-term, large-scale investment (approx. SEK 3.3 billion for the period 2019–2024).

**For further information:**
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