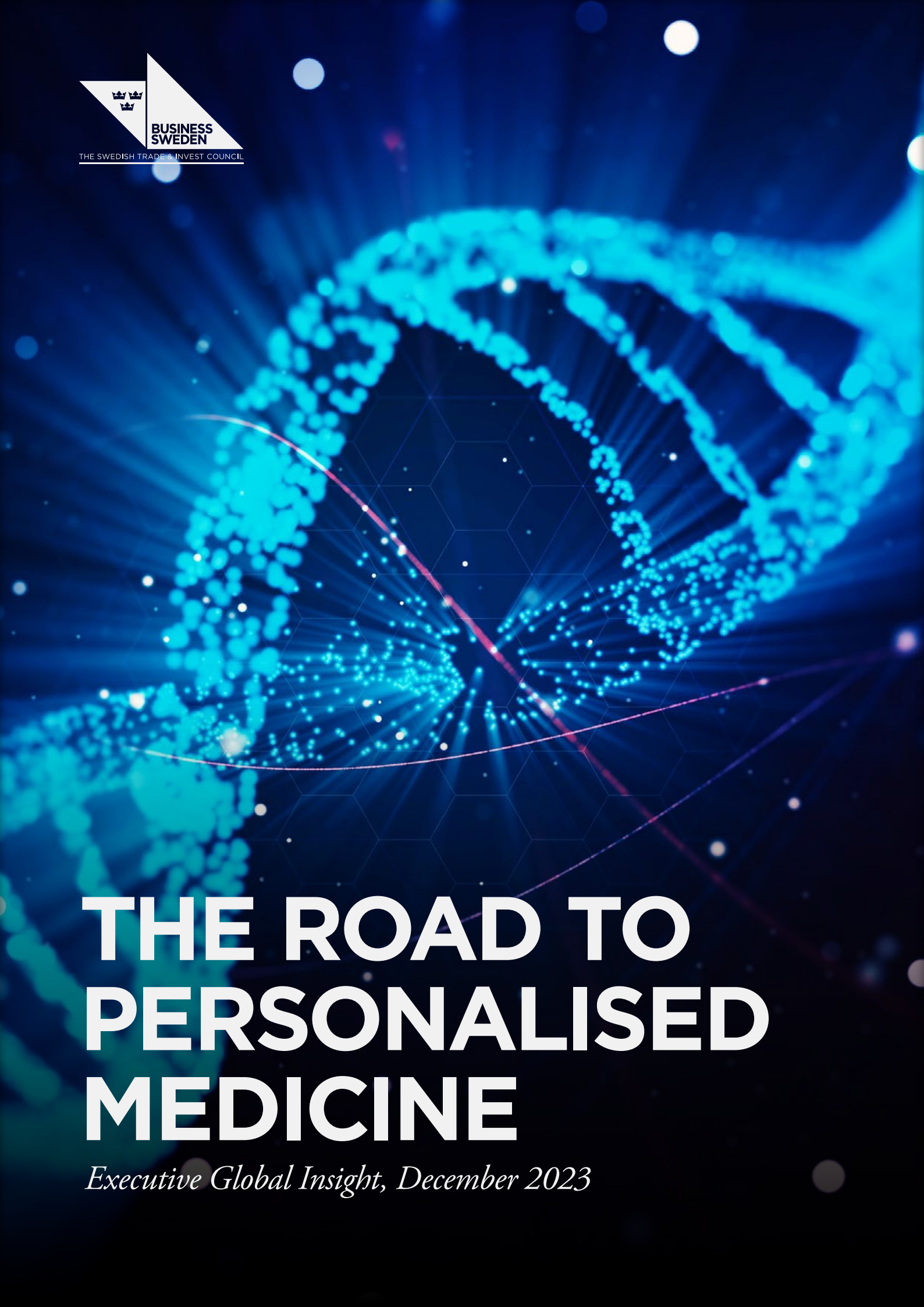


THE ROAD TO PERSONALISED MEDICINE

Executive Global Insight, December 2023

CAPTURING THE DATA-DRIVEN SHIFT TO PERSONALISED MEDICINE

Healthcare systems across the developed world are under continuous stress. Ageing populations, rising numbers of chronic patients, and staff shortages — these are just a few of the factors that drive the need for more prevention and increased effectiveness of delivered care.

Personalised medicine is an evolution of current clinical and pharmacological praxis that takes the individual characteristics of each patient into consideration to arrive at personalised diagnosis, prevention, and treatment plans. The inclusion of health data (from sources such as Electronic Health Records and Digital Health Technologies) in this can amplify the understanding of medical conditions and enable further prevention and targeted treatments.

Several enabling factors that are needed for implementing data-driven personalised medicine (DDPM) come into play, including genomics databases, health data infrastructure, personalised pharmaceutical products, and favourable regulatory and payor attitudes.

HOW MATURE ARE GLOBAL MARKETS?

In this report, we have looked at the above factors by interviewing healthcare practitioners and experts in three regions – as well as by analysing secondary data – to gauge the varying maturity levels for implementing DDPM across the globe.

The Americas region is dominated by what happens in the US where personalised medicine builds on the country's vast experience in genomics. Here, we see a clear commercial model and payor support for certain genetic tests in diagnosis and a link to personalised treatments. However, the data perspective remains a challenge as data is siloed and difficult to merge across the system and its stakeholders.

While there are many interesting genomics initiatives in Europe, genetic tests are not prevalent in clinical practice and the access and management of genetic data is considered complicated. EHR-implementation is high, but the lack of common standards makes sharing problematic. This is, however, being addressed by initiatives aiming to harmonise both infrastructures as well as regulation.

In the highly varied landscape of APAC, Singapore and Australia have clear plans for implementing DDPM with world-leading genomics facilities, national data sharing initiatives and a favourable regulatory environment. Other countries, such as South Korea, China and Japan have made advances in genomics but less so when it comes to enabling data collection and sharing.

THREE STEPS TO ACCELERATE THE SHIFT

Data-driven personalised medicine has the potential to solve important pain points in healthcare by improving precision and effectiveness, prediction and prevention, and further enhance R&D. To facilitate and accelerate the uptake of DDPM, the healthcare industry should consider the importance of:

- In the development phase of solutions for data collection, focus on ensuring transportability, interoperability, and compliance with emerging standardisation protocols
- Facilitating implementation of new solutions and help practitioners sort, analyse, and act on data.
- Fully understanding how local conditions are shaped by legislation, local business models, and often unique systemic pain points, to successfully integrate new technologies.

Sweden's life science sector is in many ways a frontrunner in the field of DDPM, but needs to further embrace the shift by monitoring developments and adapting to a more personalised approach to health.

BUSINESS SWEDEN

USING DATA TO TACKLE A GLOBAL HEALTHCARE CONUNDRUM

The developments in data-driven personalised medicine on a global scale present significant opportunities for Swedish companies. The pace of progress may vary, but the global trend is towards integrating data-driven approaches to optimise healthcare delivery and outcomes.

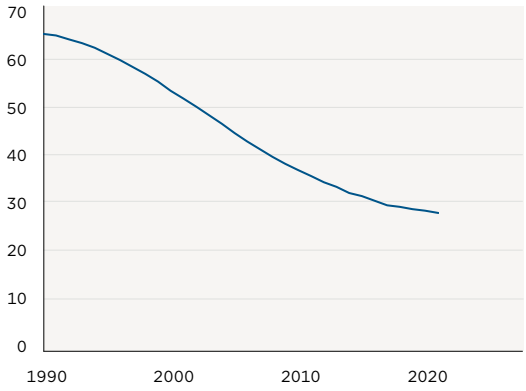
Looking back over the last century, the delivery of healthcare has undergone tremendous development. Life expectancy has increased dramatically (from 51 years in 1960 to 71 years in 2021[1]) and infant mortality rates have fallen rapidly across the world (from 65 per 1,000 live births in 1990 to 28 in 2021[2]). Driving this development, along with improvements in hygiene and nutrition, are technological and pharmaceutical innovations that have changed the way diagnoses and treatments are carried out.

Nevertheless, despite the enormous progress many healthcare systems across the developed world are facing big challenges in continuing to provide high-quality care. Some of these include:

- Demographic shifts with an increasing proportion of elderly populations as many live longer lives (In the OECD, 8 per cent of the population was aged 65+ in 1960 – in 2022, that number was 18 per cent[3])
- More resources are needed to care for an increasing number of people living with chronic disease thanks to progress in the care and treatment of previously life-threatening conditions, especially in areas such as cancer.
- Labour shortage across clinical and auxiliary roles is straining healthcare organisations and is cited by professionals in the sector as one of the most pressing issues they face today (according to the WHO, there could be a shortfall of 10 million health care workers by 2030 across the globe[4])

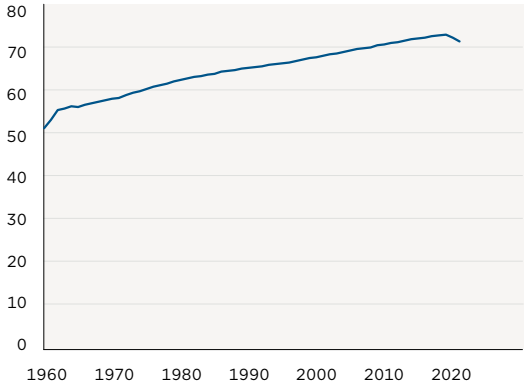
These factors combined mean that the financing and organisation of healthcare delivery is currently under pressure and, according to healthcare experts Business Sweden has spoken with, there are few signs that this pressure will abate any time soon. As most advanced healthcare systems around the world are experiencing constraints in terms of access, volumes, and affordability, most of them are currently trying to solve a conundrum of short-term issues, such as how to fill shifts as well as long-term and systematic issues, such as how to attend to the medical needs of a growing group of older patients. Personalised medicine and data-driven solutions could offer a solution

INFANT MORTALITY RATE PER 1000 LIVE BIRTHS



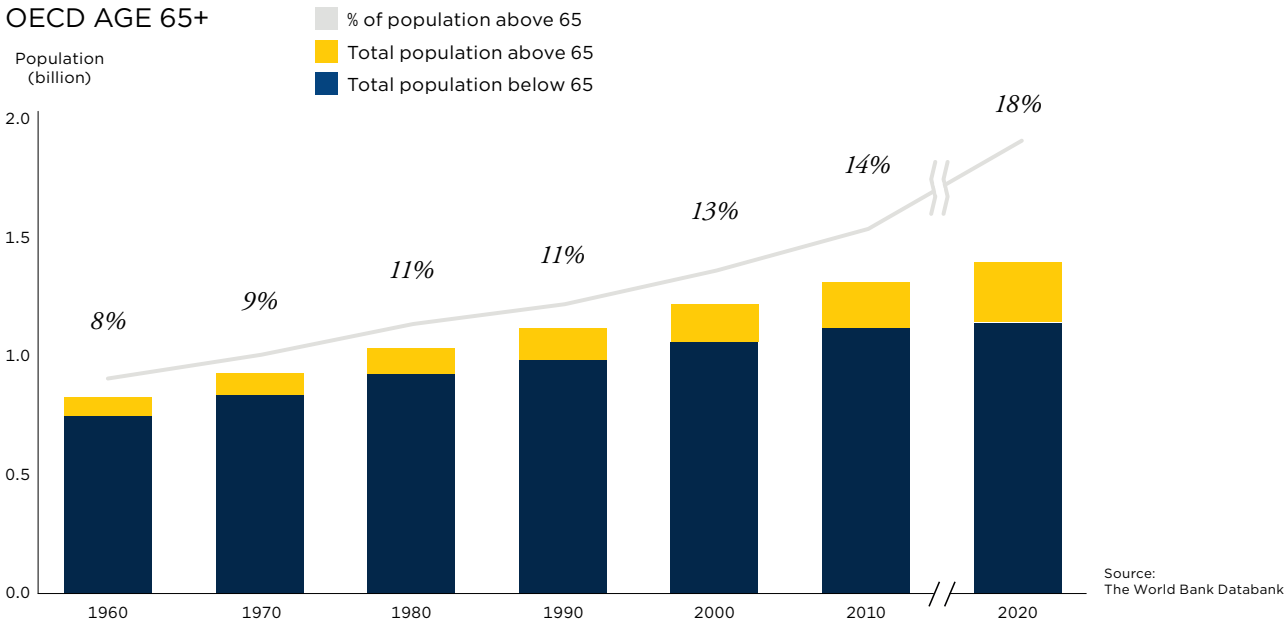
Source:
The World Bank Databank

LIFE EXPECTANCY AT BIRTH (YEARS)



Source:
The World Bank Databank

[1] The World Bank DataBank
[2] Ibid.
[3] Ibid.
[4] Health workforce (who.int)



BEHIND THE SCENES OF PERSONALISED MEDICINE

Although the development might be slow and complex, the healthcare sector can point to significant returns and improved clinical results when it deploys new innovations and ways of working. Personalised medicine is a case in point. This emerging practice means that healthcare is adapted to each individual patient based on their genetic profile, as well as environmental and lifestyle factors.

Essentially, the method involves looking at the characteristics of each patient and arriving at a personalised diagnosis, prevention, and treatment (whether pharmacological or other) as opposed to a "one-cure-fits-all" approach.

Genomic screening through next-generation sequencing is at the heart of personalised medicine. This method is used to conduct a broad genomic diagnostic on patients, to date mainly cancer and rare disease patients. The data is analysed, and the results are used as a base for individually adapted treatments.

Progress in diagnostics and multiomics means that scientists and clinicians can use detailed knowledge of each patient to tailor treatments by, for example, selecting certain active substances and dosages in medications. Medicines based on the molecular makeup of patients have been prescribed for several years now. In the US, for example, about a third of all new medicines approved are personalised medicines.

The potential benefits are huge: previously incurable cases can[5] now be treated and can be done so more quickly and with fewer side-effects. For healthcare systems, the benefits are equally beneficial – diseases can be precisely diagnosed, prevented, and treated, potentially leading to efficiencies previously unattainable.

This shift in the healthcare sector is likely to affect the entire ecosystem of suppliers: from those delivering large and complex medtech equipment to more rudimentary consumables; from genomic test providers and laboratories to pharmaceutical companies; from providers of image analysis software to patient wearables. There are important implications for the entire industry.

Experts interviewed by Business Sweden agree that the shift towards a personalised approach is inevitable. Among them is a representative of the German Aerospace Center (DLR) and the International and European consortia for Personalised Medicine (ICPerMed and EP PerMed), says: *"Personalised medicine or similar concepts, like precision medicine or P4 are actually modern medicine utilising the latest developments in all biomedical and diseases-specific areas as well as the available technologies of which some are beyond the usual biomedical range."*

[5] Personalized medicine at FDA, PMC, 2022

ENTERING THE DATA AGE

Originally, personalised medicine focused on genetics and what was known about specific gene variations. This still forms the basis of personalised medicine but the vast amount of data now being generated in healthcare has multiplied the possibilities and taken personalised medicine to the next step, known as data-driven personalised medicine (DDPM).

Data-driven personalised medicine leverages large-scale data analysis, including genetic information, clinical records, and patient-reported data, to tailor medical treatments and interventions to individual patients. It allows the integration of multiomics with new tools and methods in data analytics, AI and machine learning, digital health platforms, data-generating wearables, remote monitoring devices, and EHR and other data sharing initiatives.

Coupled with the emergence of personalised diagnostics and targeted treatments, especially from the pharmaceutical sector, this development can lead to more precise, targeted, and effective interventions, with improved patient outcomes and optimised resource allocation. Beyond that, it is also expected to greatly increase the possibilities for prediction and prevention, saving future costs and suffering. All the while contributing to further research and innovation through a continuous cycle of data collection, analysis, and discovery and enabling continuous advancements in medicine.

For healthcare systems struggling with the challenges outlined above – such as an overstretched workforce and an overload of patients – the implications and benefits of data-driven personalised medicine could be decisive.

FOUR ENABLERS FOR IMPLEMENTING PERSONALISED CARE

ADVANCES IN GENOMICS

New technologies, often referred to as genomics and multiomics, make it possible to use patients' genetic information to better diagnose and treat conditions – and are at the core of personalised medicine.

PERSONALISED MEDICINE IN DRUG DEVELOPMENT

Pharma products constitute one of the key pillars of personalised medicine as directed treatments and adapted pharmaceutical products are the result of a personalised approach; the evolution and development of these types of pharmaceutical products will have a decisive impact on the evolution of personalised medicine.

HEALTHCARE DATA INFRASTRUCTURE

Countries with well-developed electronic health record systems, interoperable health information networks, and national or regional health data platforms are better equipped to implement and scale personalised health approaches. Two proxies for this are the implementation of national EHR systems, as well as national Health Data Hub initiatives.

REGULATION AND FINANCING

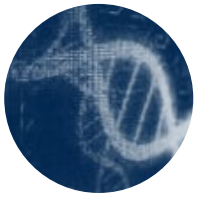
Adequate regulation and funding models are necessary for the continued evolution and adoption of data-driven personalised medicine. Countries with clear guidelines on data privacy, genomic testing regulations, and funding and reimbursement mechanisms for both data collection and personalised interventions could be more conducive to the long-term evolution of personalised health.

Global healthcare systems are at different stages of the shift to a personalised medicine approach and reveal different gaps in the expertise, knowledge, technology, or solutions required to take the next steps on this journey. As such, different regions and markets present different opportunities and challenges in the transition.

3 KEY STRENGTHS OF SWEDISH LIFE SCIENCE

ADVANTAGE SWEDEN

The key players in Sweden's pharmaceutical and medtech sectors are frontrunners and overall well-equipped to capture the emerging opportunities. Sweden combines the availability of extensive real-world evidence data with a mature AI ecosystem and has innovative technologies in most areas of personalised medicine.



PRECISION MEDICINE

ATMP
Sweden holds the third most companies in ATMP in Europe, only behind UK and Germany. Karolinska Institutet is a leading European institution for the number of affiliated researchers in cell and gene therapy. *

CCRM Nordic
A national collaborative infrastructure to support commercial development and manufacturing of ATMP. CCRM is co-located in the Life Science cluster GoCo together with leading companies across the ATMP value chain

DIGITAL HEALTH

Connected Health
Sweden has a national policy aiming to be world leading at healthcare digitalization by 2025, and even has its own eHealth agency

Center for rural medicine
Unique access to health data for research, with national quality and patient registries and +150m samples collected in biobanks.

Medical Imaging
The East Sweden region holds a European leading cluster for image analysis, led by innovation environment Visual Sweden, University of Linköping and Region Östergötland.

DRUG DEVELOPMENT

Drug Discovery
Sweden has a strong position in drug discovery and development, from early discovery to phase III, and parades project portfolios with distinct commercial value.

Drug Formulation
The country has a large share of companies in drug formulation and development led by the center of excellence SweDeliver

Bio-Manufacturing
Global pharmaceutical companies are choosing Sweden for locating bio-manufacturing sites.

The country hosts national infrastructure to support early-stage biomanufacturing

Testa Center – a national testbed for early stage pre-GMP manufacturing

NorthXBiologics – national infrastructure for support and services in GMP biologics manufacturing.

Source: ATMP Sweden Baseline Report, MSC, (2020)*, SwedenBio Pipeline Report (2023)

STATE OF PLAY: A GLOBAL OVERVIEW

EMEA

ADVANCES IN GENOMICS

Over the past decade, many European countries have developed genomic data banks and set up national genomic strategies. Investments and capabilities vary vastly and are often fragmented at the national and often regional level.

The strategy and approach to genomics and genomic medicine in each country follows the structure of healthcare systems. Two examples are the UK and France, both of which organise and run their public healthcare systems at a national level.

The UK has prominent biobanks, mainly the UK Biobank (established in 2006) and Genome UK. The public healthcare provider in the UK, the NHS, has leveraged these initiatives and introduced major national infrastructure in 2018 to support the integration of genomics in clinical use.

In France, *France Medicine Génomique 2025* is a programme for the collection of genomic data through comprehensive molecular testing of patients since 2016. The strategy aims to integrate genomic medicine into the French national healthcare system.

In some of the countries that structure their healthcare systems at the regional level, such as Spain and Italy, there are also innovative approaches and tests around genomics although at a smaller scale.

Looking at Germany, however, there is lag with other European countries when it comes to genetic diagnostic capabilities. This is mainly attributed to restrictive regulation that was to an extent mitigated in 2021 when the national strategy for genomic medicine was introduced.

While national data banks are in place in Europe, and new data is continuously generated, the access and management of this data remains a challenge. Initiatives and investments on the continent are generally described as uncoordinated and fragmented and the lack of large-scale cross-border access to data is seen to impede the development of data driven personalised medicine.

To mitigate this, several initiatives are running to overcome issues with cross-border sharing of data and fragmented investments. Personalised medicine is a main priority of the European Commission's research agenda.

One example is the '1+ Million Genomes' initiative aiming to create a data infrastructure for genomic data and implementing common national rules enabling cross-border data access. It is supported by The Genomic Data Infrastructure (GDI) project, which aims to create infrastructure to provide access to genomic and related phenotypic and clinical data across Europe.

Other initiatives are ICPerMed and EP Permed, EU-funded platforms bringing together over 50 European and international partners representing ministries, funding agencies and the European Commission, with the aim to align and encourage joint efforts in personalised medicine research and implementation.

Overall, genetic screening is not yet widely integrated in the healthcare provision of most European countries. There is a lack of knowledge and therefore a need for education and training of healthcare professionals in this area. *"The medical need and benefit are demonstrated for first PM approaches, but their implementation in healthcare needs to be developed jointly with healthcare providers to increase acceptance and feasibility,"* says a representative of the French National Research Agency (ANR).

This, coupled with the fact that funding models of European healthcare systems are not yet prepared to integrate the cost, risks hampering development and business opportunities in this field.

"In Europe there is resistance to starting genomic screening programs. Screening is closely linked both to diagnostics as well as to treatment as the purpose of screening program should be to identify diseases for which a treatment is available. As a consequence the screening cost should be considered in relation with the treatment and not only as part of the diagnostic path." says a representative of the Italian research funding organisation Fondazione Telethon.

Markets such as the UAE present somewhat different opportunities. In 2023 the UAE launched a national Genome strategy, including the Emirati Genome Programme aiming to collect 1 million samples from their citizens over the course of ten years, taking a step closer toward personalised treatment. The strategy was developed in public-private partnership with M42, the largest healthcare company in the Middle East.

HEALTHCARE DATA INFRASTRUCTURE

Electronic Health Records (EHR) are considered the cornerstone of digital healthcare infrastructure. The implementation of interoperable EHR systems is crucial for the shift to personalised medicine. On the one hand, because it will allow for collection and sharing of data, and on the other, because it is necessary to ensure proper follow-up and monitoring of personalised medicines and therapeutics. *"Proper EHR implementation will be a gamechanger, as there will be no additional cost for collecting data,"* Fondazione Telethon continues.

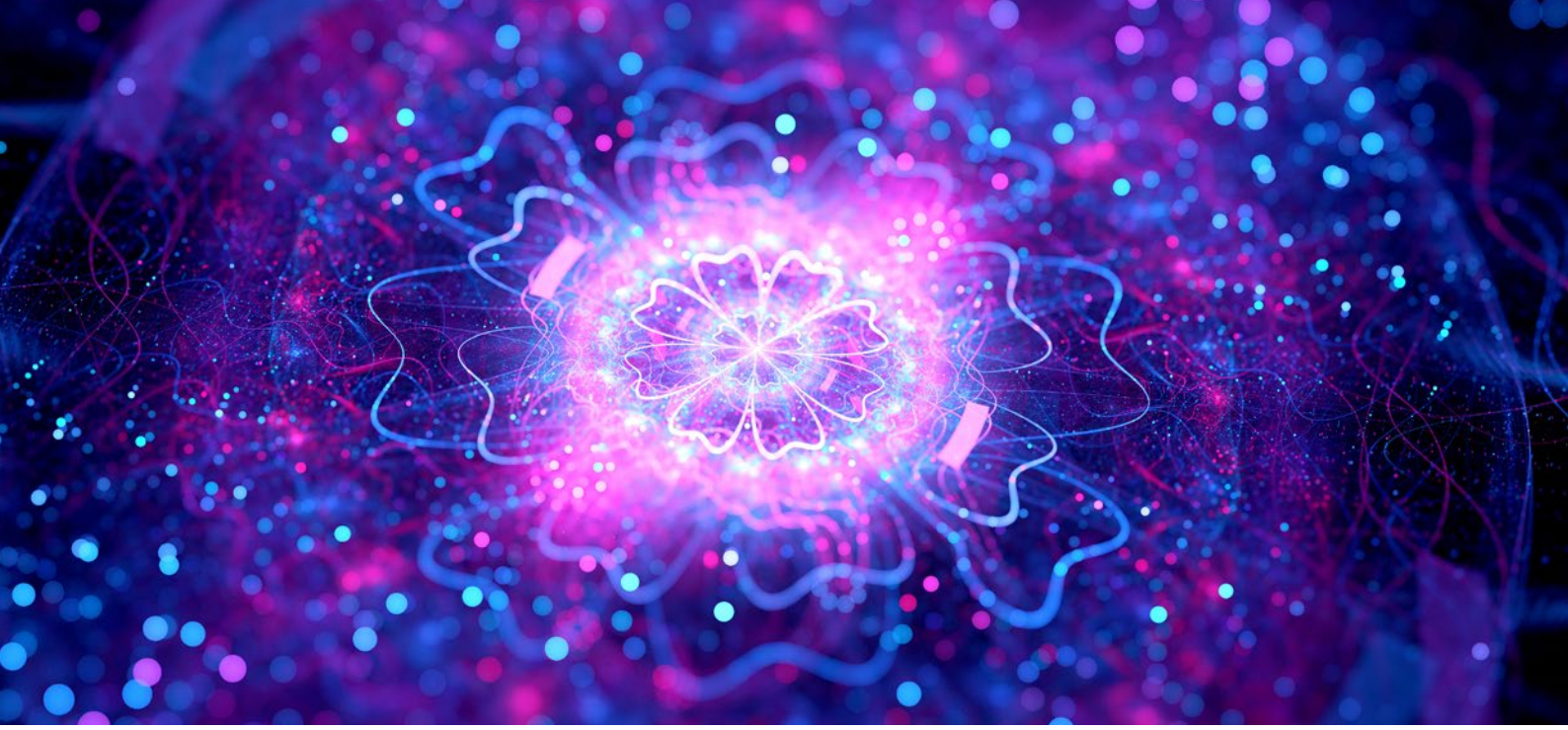
Several sources agree that while most European countries have implemented digital health record systems to some extent, these are rarely interoperable, making it difficult for patients to access their data, and often impossible to share it between providers let alone countries. According to a study[6] by the European Commission, some exceptions are Finland and Estonia, and certain autonomous regions in Spain. Many European countries have a decentralised healthcare structure, and that fact often takes the blame.

One initiative to counter this is the Data Analysis and Real-World Interrogation Network DARWIN EU, launched in 2022. DARWIN is led by The European Medicines Agency (EMA) and is described as a first step toward incorporating Real-World Evidence (RWE) into drug evaluation. As RWE is based, in part, on analysis of EHR data, the project depends on the use of these data from European countries.

Looking beyond the EU, Israel has made advances in data sharing and since 2018 allows anonymised EHR data to be accessible to researchers, entrepreneurs, and healthcare providers. However, the country faces similar challenges in terms of interoperability. According to a recent study, only 20 per cent of healthcare providers in Israel had fully integrated their medical records with the new EHR system[7]. In 2022, the NHS committed GBP 2 billion[8] to a digital transformation plan for the NHS, with a focus on supporting the implementation of interoperable EHR in all NHS trusts. The UAE is implementing a centralised EHR system, currently in the process of integrating with the two major regional EHR systems in the UAE.

An interoperable network of EHRs would also significantly facilitate market entry for Swedish digital health companies into other markets and would reduce the need to adapt their products and business models.

[6] Interoperability of Electronic Health Records in the EU | Shaping Europe's digital future (europa.eu)
[7] Electronic Health Records Implementation in Israel Faces Important Challenges | Anthony Lucas | The Blogs (timesofisrael.com)
[8] A plan for digital health and social care - GOV.UK (www.gov.uk)



REGULATION AND FINANCING

Clearly defined rules and common standards open up markets and are facilitators for international business. In this respect, the regulatory landscape in Europe is generally stable and currently centres on two legislations: GDPR and EHDS.

GDPR is considered stricter than existing comparable regulation – such as the US Health Insurance Portability and Accountability Act (HIPAA) – and, as a result, there is concern that this has led to lower use of European health data in international studies, making European citizens underrepresented in international research. However, it is also considered a cornerstone of personal data management and, as such, a prerequisite for data driven personalised medicine.

Whereas GDPR serves as the foundation for privacy protection in Europe, the EU is taking the next step towards "unleashing the full potential" of health data by the planned implementation of EHDS. *"This is a stratospheric step, and will be a gamechanger for the whole ecosystem, paving the way for quality of care,"* says a representative of the French Health Ministry.

From an industry perspective, harmonisation and standardisation – such as provided by EHDS – is expected to simplify the expansion into new markets. EHDS is also expected to promote innovation since it will provide legal access to electronic health data. The learnings from implementing EHDS also give the EU better capacity to manage cross-border collaboration with non-EU countries.

The European Commission expects that EHDS will generate additional 20-30 per cent growth in the digital health market and that it will facilitate savings of over EUR 10 billion in healthcare as well as in R&D and policymaking, in the coming ten years from implementation[9].

It can still be argued that European markets have come the furthest in providing a clear framework that will allow data driven personalised medicine to thrive, but whereas the GDPR and the EHDS are considered comprehensive, the level of application and implementation vary considerably from market to market. According to a recent French official study,[10] GDPR has unlocked significant progress, but many countries are still not in compliance with all aspects of the regulation.

Another important enabler for data driven personalised medicine is access to harmonised and standardised data from digital medical devices, such as sensors and other remote monitoring technologies and apps and other solutions enabling patient reported outcomes.

The EU has also initiated the process of harmonising the national criteria for health technology assessment for digital medical devices by launching a task force in October 2022. At the time of writing only three countries (France, Germany, Belgium) have such a framework in place, so one should expect these to influence EU standards.

Despite the varying degree of compliance with EU regulation, the European markets present a relatively stable and predictable environment for companies operating within the field of DDPM although some sector representatives have expressed the need to adapt and rethink regulation for personalised medicine, as well as the methodology for risk-benefit assessment in clinical trials and RWE.[11]

Advanced healthcare markets in the Middle East such as UAE and Israel have also adopted data protection laws specifically adapted to healthcare. UAE adopted a federal law in 2019, bearing similarities to GDPR and Israel has a privacy act in place since 2017. Israel is currently drafting a new law on data sharing which aims to increase interoperability through standardisation, seemingly opting for the FHIR standard.[12]

[9] https://ec.europa.eu/commission/presscorner/detail/en/fs_22_2713
[10] Mise en place d'une organisation digitale (esante.gouv.fr)
[11] Life Sciences – The Era of Personalised Medicine (europa.eu)
[12] Everything You need to know about the health data mobility law – Outburn

WHAT IS EHDS?

The European Health Data Space (EHDS) is an EU regulation and digital data ecosystem proposed by the European Commission aiming to give patients in the EU more control over their health data, and to make it easier to share and access different types of health data. EHDS is set to be enacted in 2025 and should cover both healthcare (primary use) and research, innovation and decision-making (secondary use). FHIR is expected to play a central role. A recent study commissioned by the European Parliament's Committee on Industry, Research and Energy (ITRE), states that:

"The Fast Healthcare Interoperability Resources (FHIR) is a candidate to play a key role. It is an application programming interface (API) for exchanging electronic health records (EHR). It includes descriptions of data formats and elements (profiles), and appears to have the potential to reach critical mass in terms of usage. The United States has been making production use of FHIR for many years […} various FHIR data profiles are already available for instance in Denmark, Germany, France, Italy, and the Netherlands.[13]

ABOUT GDPR

The General Data Protection Regulation (GDPR) is a comprehensive data protection and privacy regulation enacted by the EU in 2018. It aims to safeguard the personal data of individuals within the EU by establishing strict rules for how organisations collect, process, and store this information. Non-compliance can lead to fines.

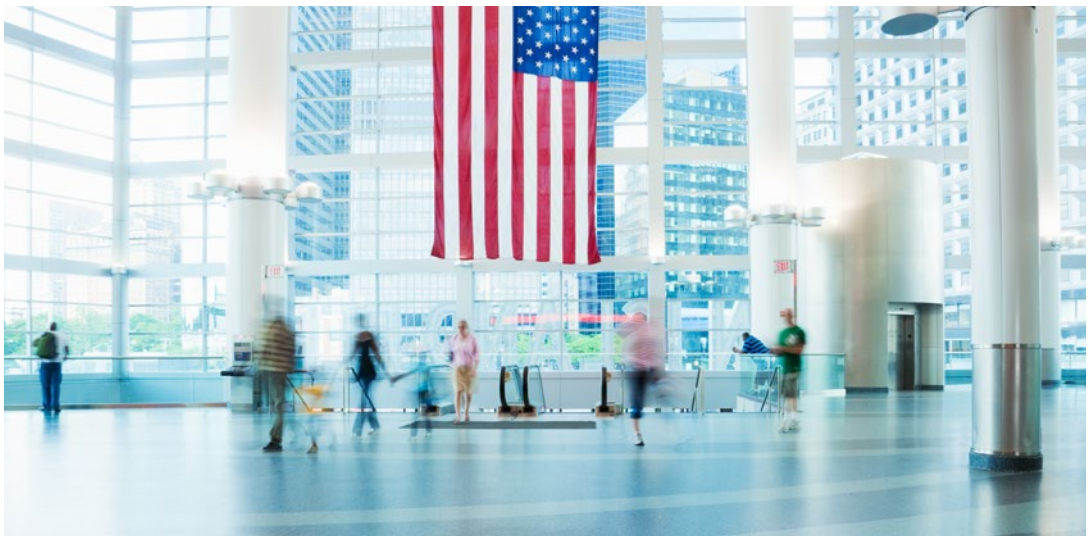
SPOTLIGHT ON THE US AND EU: PERSONALISED MEDICINE IN DRUG DEVELOPMENT

The pharmaceutical industry is at the core of personalised medicine and the drug approval process is also adapting to the data driven nature of personalised medicine. While regulation and funding are still to a large extent based on traditional diagnostics based on individual tests, personalised medicine technologies such as next generation sequencing contain massive amounts of tests, and therefore require a different regulatory and reimbursement approach. The FDA and EMA communicate around their work to adapt the regulatory environment and collaborate and share best practices.

The EMA states in their Regulatory Science Strategy to 2025 [14] that *"the advent of big data opened up new sources of information on the use of medicines in healthcare settings. Regulators needed to take action to address the challenges arising from collecting and processing these data from patients."*

In an annual report [15] on the progress of personalised medicine as measured by FDA drug approvals, the Personalised Medicine Coalition (PMC) noted that for 2022 the rate of approved personalised medicines amounted to 34 per cent of all drug approvals. The rate has been fluctuating between 25 and 42 per cent since 2015. In 2005 that number was 5 per cent.

[13] The European Health Data Space (europa.eu)
[14] Advancing regulatory science in the EU – mid-point report published | European Medicines Agency (europa.eu)
[15] Report.pdf (personalisedmedicinecoalition.org)



AMERICAS

ADVANCES IN GENOMICS

Personalised medicine in the US has primarily focused on genomics, an area in which the country has been at the forefront both in terms of investments and resources. A major investment in the genomics space took place in the 1990's with the Human Genome project, which was a scientific effort to generate the first ever sequence of the human genome. In more recent years, the Precision Medicine Initiative has allocated investments and resources to accelerate the application of genomics data with other data to personalise treatments for patients. This has resulted in tremendous success within oncology, bringing practical applications to market.

"Europe has a strong backbone of research and is the source of massive advancement of the gene therapy space, but many products come to market through American companies. Americans are good at selecting the good science and scaling it up and selling it," adds a representative of Fondazione Telethon.

More recently, "All of Us" is a research programme inviting one million Americans to contribute to one of the most diverse health databases in history. The database will create opportunities to accelerate the development of personalised medicine by understanding treatment effects for people of different demographics and better understand genomic technologies and the risk factors for certain diseases. The programme is an initiative by the National Institute of Health and has been allocated USD 1.5 billion over ten years since its inception in 2016.

While there has been a long and fruitful history of genomics in the US, primarily with commercial incentive models for applying tests and the development of pharmacological products in conjunction with investments in research, there are still challenges to overcome within genomics and personalised medicine in clinical applications according to our expert interviews.

Primarily, these relate to the lack of awareness (among patients and clinicians alike) as well as the availability of genomic tests. Consequently, clinical adoption is currently not at its full potential, especially as costs of genomic tests remain high given that current reimbursement schemes do not always adequately cover the costs of the tests. The lack of clear reimbursement policies can be a barrier to wider adoption as healthcare providers may be less inclined to invest in personalised medicine technologies without clear coverage. However, at the moment, oncology stands out as an area where coverage and awareness are higher.

"Precision Medicine in the US primarily focus on genomics today which has come the furthest in terms of development, research, and clinical application. The area has also received the most funding from the National Institute of Health" – Head of Genomic Division at leading research institution

HEALTHCARE DATA INFRASTRUCTURE

The US has a 96 per cent implementation rate of EHRs at US hospitals and the system has the infrastructure for implementing personalised medicine given the abundance of data. Clinical decision support tools (CDS), and other analytical platforms for treatment optimisation, are growing quickly and, according to our interviews with experts, are used to personalise patient care even further.

Most commonly, CDS tools gather data from EHRs and give indications to clinicians on how

to optimise the treatment or care plans for specific patients. Further augmenting this development is the trend of using remote patient monitoring (RPM) and remote sensors for capturing health indicators to provide additional patient insights.

While the US has made many significant strides in terms of infrastructure for personalised medicine, the main structural hurdle in the US is that datasets are of a local character, with data being highly siloed and not shared across the many stakeholders within the healthcare system. Furthermore, health records are difficult to combine due to the lack of a common ID for patients. Even if regulatory framework HIPAA requires the creation of a national identifier, there is existing legislation that prohibits the Department of Health and Human Services from funding such adoption.

Moreover, even if EHRs are implemented, they tend to lack the ability to analyse and configure data needed for personalised medicine[16]. This will require investments and resources from healthcare systems and EHR providers to expand the functionality to lay the foundation for clinical application of full-scale personalised medicine.

REGULATION AND FINANCING

The US main patient privacy regulation is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA aims to protect the patient by giving the right to access data and limits the access for other stakeholders. HIPAA should be seen as a necessity to comply with for companies looking to enter the US market. Furthermore, the 21st Century Cures Act (Cures Act) was passed in 2016 with the goal of increasing innovation and competition in the industry by giving patients and providers secure access to information. The act puts the patient at the centre when it comes to product development and market approval processes. An enhancement of the legislation from a personalised medicine perspective is the Advancing Real-World Evidence (RWE) programme leveraging real-world data for clinical trials initiated by the FDA.

The FDA is the US agency for market approval of medical products and drugs. Like many other organisations, the FDA is adapting new practices to ensure innovative and novel treatments and technologies within personalised medicine can safely be accessed by patients and clinicians. In addition, the agency also encourages data sharing initiatives for personalised medicine, with the FDA initiated cloud based community research and development portal for bioinformatics.

All in all, the regulatory landscape and regulators are welcoming personalised medicine initiatives and companies within the space to enter the market. In 2019, FDA approved the first digital personalised medicine device platform tool as a way of accelerating adoption. In addition, as part of the PMI, FDA reviewed the regulatory landscape for Next Generation Sequencing (NGS) and created a new market approval process for these types of tests and have thereafter also launched data sharing initiatives for research within this field.

PAYORS

According to the Personalised Medicine Coalition, one of the key challenges for the development and clinical application of personalised medicine is payor coverage.

There is an ongoing debate on what should be covered in terms of personalised medicine as payors are challenged to make a different assessment of the effects compared to conventional tests and treatments. According to our interviews, it is fundamental to payors, including the Centers for Medicare & Medicaid Services (CMS) that the effects of any treatment or test are evidence-based to ensure increased quality of care and lowered costs to the overall system.

As a result, current coverage focuses on areas with a clear link between test and treatment, such as those in oncology, as treatments in this area have demonstrated benefits over time.

Therefore, if there is a clear link that a genetic test or a personalised treatment lowers potential costs or improves care outcomes, payors have all the incentives to provide coverage.

[16] PMC The Personalised Medicine Report Opportunity Challenges and the Future.pdf (personalisedmedicinecoalition.org)

APAC

ADVANCES IN GENOMICS

Advanced healthcare markets in the region, such as Singapore and Australia, have taken major strides in incorporating personalised medicine into their national health strategies. They have established systems for covering data collection, reporting, storage, transfer, and analysis. These activities are efficiently facilitated through national portals, which also help healthcare providers to secure patient consent while delivering personalised services.

Singapore leads the way in genomic research and the advancement of personalised medicine. The National Precision Medicine (NPM) Strategy, spans three phases. Phase I established a Singaporean reference database containing 10,000 genomes (SG10K). In phase II, genomics is to be embedded into the healthcare provision. Phase III aims to establish population-scale genomics and implement personalised medicine by 2027. Canada-based AI enhanced drug discovery company Cyclica has a partnership with the Genome Institute of Singapore, and is an example of how the healthcare system is open to public-private partnerships. Singapore is also exploring the use of pharmacogenetic testing in private GP practices.

"Slowly but surely, genomic medicine is transforming our healthcare system at different points of the care pathway to enable more personalised healthcare advice and treatment, earlier interventions, better treatment outcomes and cost effectiveness."

– Singapore Ministry of Health

Australia is also at the forefront of genomic research and personalised medicine, with a National Genome Database and a National Genome Project, and the Australian government has crafted a National Strategic Action Plan for Personalised Medicine. Besides this, Australia is exploring pharmacogenomics to personalise medication choices. Public insurance covers genetic tests for certain hereditary conditions, making personalised healthcare accessible through Medicare, the national healthcare scheme.

"Our healthcare system is admired internationally, our medical research is of high standard, and recent investments in the sector aim to close gaps of health disadvantage, implying that Australia can realise the opportunities and benefits of personalised medicine." – Leading pharmaceutical company

South Korea has made significant progress in genomics research and healthcare infrastructure. It boasts a National Genome Database and National Genome Project, with centres of excellence dedicated to genomic research. While gene therapy programmes are absent, the country is actively involved in gene-based drug discovery and genome editing research. Public genomics initiatives are funded through the Ministry of Health and Welfare, and the nation has invested heavily in DNA sequencing and analysis infrastructure. There is some health insurance coverage for genetic testing.

Other countries in the region such as India, China and Japan are in the process of stratifying populations in ongoing large scale genomic studies.

HEALTHCARE DATA INFRASTRUCTURE

EHR adoption in the APAC region is on the rise, driven by government initiatives to digitise healthcare records. Advanced healthcare systems like Australia and Singapore both see fairly advanced electronic health record adoption. While lacking a national EHR database, work towards standardisation is being ramped up at the national level.

In Australia and Singapore, EHR adoption covers all aspects of data management, including collection, reporting, storage, transfer, and analysis. National portals, such as the national provider portal in Australia and EMRX in Singapore, streamline the data collection process and enhance data analysis and transfer efficiency. These portals also facilitate the obtaining of patient consent for personalised services. One significant difference between these two countries is that in Singapore, The HDH Platform and Infrastructure is built and managed by the government, and in Australia, The HDH Platform and Infrastructure is built and managed by multiple private players, regulated by the government. In South Korea, the government has set-up a nodal authority on managing and standardising EHR and all the healthcare providers follow its guidelines while reporting health data via their independently launched portals.

In other markets such as Japan and China, EHR adoption primarily covers data collection, reporting, and storage, with limited capabilities in data transfer analytics. National portals for EHR facilitation are still under development in these markets, leading to data transfer occurring via patients. Data collection remains unstandardised and healthcare service providers often use their own reporting formats. Many healthcare providers using EHR in these markets report data in PDF format, making data analysis difficult.

Japan has no National EHR system or Health Data Hub in place. According to the Japanese Health, Labor and Welfare Ministry, more than 90 per cent of large hospitals have already introduced electronic medical records, but this figure falls below 50 per cent at small hospitals and medical clinics.

REGULATION AND FINANCING

Each market in the region has its own regulations and guidelines governing data use and privacy, although they may not be explicitly designed for personalised medicine or even healthcare.

Australia has stringent privacy regulations, including the Privacy Act and My Health Records Act, governing the collection and use of health-related data, with a focus on consent and data protection. In Singapore, regulatory oversight is provided by the Health Sciences Authority (HSA), and the Personal Data Protection Act (PDPA) governs the handling of personal health data. The National Electronic Health Record (NEHR) system, governed by the NEHR Act, safeguards patient health information. South Korea has data strict protection laws such as the Personal Information Protection Act (PIPA) and the Bioethics and Safety Act. Several state and territory governments have privacy legislation specifically for health data, whether held by healthcare professionals or by digital health applications. This legislation typically restricts transfer out of the country, making cloud and other offshore storage problematic.

In China the Cybersecurity Law regulates data protection and privacy to protect personal information and imposes obligations regarding data collection, storage, and cross-border transfers.

The level of promotion by payors of personalised medicine varies across the region. While payors may not be the sole driving force behind the promotion of personalised medicine, they are increasingly recognising its potential benefits in reducing adverse impacts and optimising healthcare spending.

CONCLUSION

SWEDEN'S COLLABORATIVE ECOSYSTEM A WINNING FACTOR

Data-driven personalised medicine has the potential to radically improve healthcare delivery and outcomes in the next decade. There is broad consensus that it can unlock better precision, effectiveness, prediction and prevention, and further enhance R&D efforts.

In short, DDPM has the power to address some of the most critical pain points that the healthcare sector is facing today. But there are several important hurdles that must be overcome before adoption gains momentum across the world.

The most obvious challenge is data analytics and management, which is a major area of opportunity where Swedish specialists can help accelerate the shift to personalised medicine. When it comes to current maturity levels and the varying approaches toward the implementation of personalised medicine in global markets, our assessment of the status quo in the previous chapter leads us to the following conclusions.

KEY TAKEAWAYS: EMEA

Across Europe, there are national initiatives for generating and collecting both genomic/multiomic and other health data. The current challenge is a continued lack of access to shareable data, tools and methods for analysis of vast data, and a general fragmentation of initiatives and investments. In this space, there are significant opportunities for companies offering applicable solutions for combining vast data, both in analysis, collection, and in building the infrastructure for follow-up.

KEY TAKEAWAYS: AMERICAS

The personalised medicine landscape in the US is at the forefront of genomics development and application within both clinical and research settings. Access to more data points for personalised treatments is rapidly improving with new initiatives, further research and private players entering the market at a fast pace. There are still challenges in accessing, analysing, and leveraging the siloed data, but the greatest obstacle for adopting personalised medicine solutions today is to provide proof of positive outcomes to fully gain coverage within the healthcare system.

KEY TAKEAWAYS: APAC

APAC has a highly diverse landscape and great variations due to healthcare system setup and maturity. Advanced healthcare systems such as Singapore and Australia have government-backed plans to implement personalised medicine, and comprehensive privacy regulations. Electronic Health Records (EHR) have been implemented and there are national health data sharing initiatives. In these markets, Swedish companies will find opportunities both in multiomics production as well as data analytics and management.

South Korea, China, Japan have made smaller advances in genomics, and both data collection and sharing are lagging behind. As such, data collection is where Swedish companies can help fill the gap and speed up change. It is worth remembering that China's strict laws could make it a more complex market than its neighbours. India is still an emerging market, where the opportunities seemingly lie in supporting more fundamental tasks such as digital tools for ensuring access to healthcare.

IMPACT ON THE DEVELOPMENT OF DDPM

		EMEA	*AMERICAS*	*APAC*
1	ADVANCES IN GENOMICS	→	↗	→
2	PERSONALISED MEDICINE IN DRUG DEVELOPMENT	→	↗	→
3	HEALTH-CARE DATA INFRASTRUCTURE	↗	→	↘
4	REGULATION AND FINANCING	→	→	→
		Strong potential with EDHS and centralised care delivery while interoperability and clinical use of genomic tools is low	Best in class on building and applying multiomic and treatment capabilities but development impeded by siloed data	Large variation across countries – some momentum in genomics across the region while data infrastructure is currently impeding growth

THREE STRATEGIC RECOMMENDATIONS

DATA

The harvesting of health and multiomic data from patients is crucial in all types of offerings – from wearables to consumables to genetic tests. In this respect, interoperability, and adaption of APIs, etc., is a necessity, as is the transportability of the collected data. For data collecting solutions to be future proof, they must be interoperable. Standardisation protocols are now taking shape and there is a window of opportunity to participate in this work as well as in making sure that data harvesting solutions are compliant.

USERS

Make it possible and preferably even easy for providers and systems to integrate new solutions, and make sure they can be used and run over time in the setting they are intended for. There is a clear global need for technologies and solutions that can help practitioners and providers sort, analyse and act on the collected data.

LOCAL CONDITIONS

Implementation in healthcare systems will be shaped by factors such as legislation and regulations, local business models, and systemic pain points. These factors need to be fully understood and taken into consideration for successful integration.

The Swedish life science ecosystem benefits from its firmly established multiple helix-approach that permeates the entire healthcare sector. Swedish companies are not only at the forefront of data-driven personalised care, but are also used to collaborating closely with academia and government organisations. This makes Swedish companies well-prepared for collaborative projects and positioning themselves as trusted industry partners around the world.

BUSINESS SWEDEN CAN SUPPORT YOU

Business Sweden supports Sweden's life science ecosystem across a wide range of specialty areas. We help Sweden's healthcare innovators and international investors identify partners and opportunities, navigate local market conditions and forge relationships with government stakeholders.

Whatever your needs may be – market entry strategy, M&A or administrative tasks on the ground – we stand ready to assist you at every step of your international expansion.

With a unique mandate from the Swedish government and the business sector, our global team offers strategic advice and practical support in more than 40 markets worldwide.

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