POSITION PAPER

The Development of Precision Medicine in Latvia

Added value for patients, development of human capital, and the opportunity for economic growth





Precision medicine is the cornerstone of the future healthcare landscape, where data-driven insights will guide not only patient care but also national health policies. By investing in the infrastructure and knowledge base needed for precision medicine, we can transform Latvia into a hub of medical excellence, attracting global partnerships and fostering innovation that benefits our entire society.

JOHN TULLY
Chairman and President of AmCham



Advances in science and technology make it possible to provide for a personalized approach to improving the health of each patient, offering more effective and precise diagnoses and treatments. By creating and developing a precision medicine ecosystem, Latvia will not only improve the quality of patient treatment, but also strengthen its position as a leader in biomedical innovation and precision medicine research in the Baltics.

ROBERTS MELBARDIS

AmCham Vice President, AmCham Precision Medicine work group lead



Introduction

Precision medicine (from now on – PM) is a new approach to healthcare based on individualized, patient-centered diagnostics and treatment using genetic, molecular, and clinical data. The goal is to provide each patient with the most effective treatment based on their individual genetics and physiological and clinical attributes. The successful implementation of PM depends on the cooperation of all stakeholders.

The beneficiaries of PM include not only individual patients, but the entire PM ecosystem and the country as a whole.

A healthier society ensures greater availability of human capital in the national economy supporting economic growth.

PM is a prospective field in biomedicine and one of the specialized fields in Latvia's Research and Innovation Strategy for Smart Specialization known as RIS3 specific niche "Biomedicine, medical technologies, pharmaceuticals." In the 2024 publication, "Latvija 2040: Four Scenarios for the Future", the Latvian Institute of Strategy and Economy Institutions (LASER) highlighted the fields of healthcare, medicine, and pharmaceuticals as main areas in which Latvia has a chance to succeed at the European level and which can support economic growth going forward.²

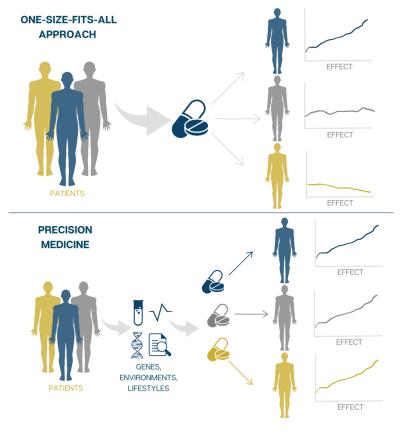
The Goal

The goal of this document is to accelerate the discussion of precision medicine's development in Latvia and invite relevant parties to joint action. Therefore, we call to establish the National Precision Medicine ecosystem coordination group or coalition involving all stakeholders that would promote cooperation between different ecosystem members and ensure the targeted development of PM in Latvia.

What is precision medicine? Its value.

Precision medicine (PM) is an innovative approach to disease prevention and tailored treatment that takes into account the differences in people's genes, environment, and lifestyle.^{3;4} PM is rapidly developing and is growing popular worldwide, revolutionizing the traditional model of disease prevention and treatment. PM places great emphasis on promoting health and preventing disease using the latest technology and data analytics.⁵

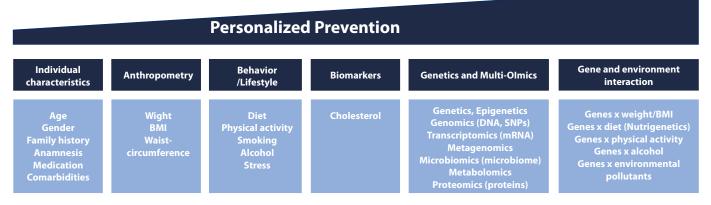
Research in oncology, cardiology, endocrinology, and infectious diseases illustrates that PM increases the value of socioeconomic productivity. The implementation of this innovation will provide patients with longer and healthier lives, creating value of hundreds of millions of euros worldwide and several tens of millions of euros in Latvia.⁶



Picture 1

The main benefits and value of precision medicine

Personalized disease prevention (avoidance) - precision medicine makes it possible to provide customized recommendations for an individual person on changes in lifestyle, diet and risk factors, in order to prevent the occurrence of diseases in the future.



Picture 2⁷

Personalized Screening

Precision medicine makes it possible to select a group of people who are most at risk of disease and apply a risk-based screening program to treat people more quickly and efficiently. For example, in Estonia, pre-screening women between the ages of 35 and 49 are offered a rapid test created in Estonia with a multifactorial risk score (polygenic risk score) to determine whether regular breast cancer screening should be performed for these women earlier than the age of 50. because 20% of aggressive breast cancers that are detected late occur precisely in this age group. 8

Personalized diagnostics/ treatment combination

The systematic integration of targeted diagnostics and therapeutics, in alignment with the concept of precision medicine. Allows to combine specific receptor expression and overall tumor load visualization, tailoring treatment approach and allowing only-treat-when-visualized (e.g. radiotheranostics). Theranostics was recently suggested as a future cancer research priority in the United States. To

Increased efficiency and economic benefit

PM can help reduce healthcare costs by identifying patients most likely to benefit from a particular treatment. It can also reduce re-hospitalizations and other costs.

Studies have found that using a PM approach can lead to significant cost-savings as targeted therapies can improve treatment efficiency, reduce the need for trial-and -error drugs, and potentially lower the costs associated with managing side effects from less effective treatments. According to a review by the Cleveland Clinic Journal of Medicine, 11 targeted therapies for nonsmall cell lung cancer have been shown to improve outcomes and reduce costs compared to traditional chemotherapy. In addition, the approach of precision medicine and gene therapy for hemophilia, spinal muscular atrophy, and cystic fibrosis proved its cost-effectiveness in several countries of the world, including Latvia, 12,13 while DPYD testing can save hundreds of thousands of euros.¹⁴ These savings reflect the potential of precision medicine in improving outcomes and optimizing healthcare spending. 15

Improved patient care

PM can help improve the quality of patient care, giving them more personalized and effective treatment. It may also promote greater patient satisfaction and quality of life. For example, a study found that oncology patients who received treatment based on their genetic profile were more satisfied with their treatment and reported higher quality of life than patients who had received standard treatment.

Innovation Promotion

PM stimulates research and the development of new technologies in medicine that can lead to the development, commercialization, and scaling of new therapies and diagnostic methods.

Potential benefits of PM:

- Earlier diagnosis of diseases
- Development of new diagnostic and treatment methods
- Personalized and adapted therapy
- Use of new technology in monitoring health data and making informed decisions
- Improving disease prevention
- Reducing the side effects of drugs

PM is a rapidly growing field with the potential to significantly improve the quality and efficacy of healthcare. Its benefits are already being delivered to patients across the world, and this trend will continue in the years to come.

PM combines both precise diagnoses and targeted interventions, and it includes a variety of diagnostic (e.g., NGS, PET-CT) and therapeutic platforms (e.g., gene, cell, proton and radioligand therapy, adaptive radiotherapy, and radiosurgery).

Precision Medicine Ecosystem

In order to successfully develop a PM approach, the cooperation of all stakeholders is essential. All relevant parties – patients and patient organizations, healthcare institutions, universities and scientific research institutes, laboratories, state institutions, industry representatives – are invited to operate in a unified PM ecosystem.



Picture 3

Comprehensive approach

- Health data, registers, and information systems
- Biobank infrastructure
- Legislation
- Ethical aspects
- Healthcare
- Informing, educating, and involving patients and the public
- Research
- Cooperation with industry and innovation
- Education and training
- Application of new, more efficient financing models
- Involvement of policymakers and a sustainable financing model for the whole ecosystem

Priority Medical Specializations and Disease Groups in Precision Medicine 16

- Oncology and hematology
- Rare diseases
- Cardiovascular diseases
- Gastroenterology
- Infectious diseases
- Diabetes
- Ophthalmology
- Neurology

The development of precision medicine in neighboring countries

In many European countries targeted implementation of precision medicine at the national level started more than five years ago. In some countries (like Denmark and Norway), national precision (personalized) medicine strategies were developed, as were national genome centers (Great Britain, Denmark, Sweden), in which the main goal is to lay the foundations for better diagnostics and improved treatment of patients using genome sequencing.

SWEDEN: The establishment of SciLifeLab (2014) and Genomic Medicine Sweden (2018)¹⁹ provides for Sweden's leading role in the development of precision medicine. Discussions are currently underway on the creation of a national precision Medicine strategy.

DENMARK: National PM strategy was approved in 2016²⁰ (2017-2020) and a renewed strategy approved for 2021-2022. The Danish National Genome Center was established in 2019.



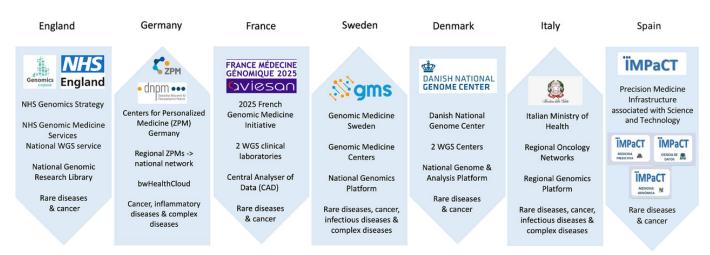
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ESTONIA: Started PM initiatives in 2014 when the Minister of Health submitted PM concept documents to the government and started the PM pilot project. Planned and coordinated implementation in the clinical environment began in 2023.

LATVIA: There is no unified or coordinated action in the field of precision medicine. There are several activities of ecosystem participants.

LITHUANIA: In 2023, started work on the feasibility study of personalized medicine, which is planned to be considered by the government in the fall of 2024.¹⁸

The implementation of PM in Latvia is possible according to a top-down, bottom-up, or hybrid approach.²¹



Picture 5²²

Taking into account its limited resources, Latvia should follow the best practices of other countries and choose a PM development strategy appropriate to its situation. Cost-effective initiatives should be sought at the national level and within the ecosystem: the fusion of PM research and PM clinical application infrastructure is a leading example, as PM's existing and newly created infrastructure are used for both scientific research and patient diagnosis and treatment.

There are conceptual and structural challenges in implementing personalized medicine. Some of the examples

include: the need for continuous competence development of medical care personnel on the advantages and limitations of genomic profiling; collaboration between physicians and pathologists; timely reporting of test results; evaluation of the clinical impact of comprehensive genomic profiling; patient access to the most appropriate and innovative therapies; the strengthening of genomic and bioinformation databases.²³ Therefore, in Latvia it would be necessary to agree on a potential PM pilot project in at least one of the priority areas specified in the Public Health Guidelines for 2021-2027.

Conclusions and recommendations

So far, several parts of the Latvian PM ecosystem have taken the first steps in PM development: work is underway on legal regulation (e.g., Secondary Data Law and Biobank Law), the creation of health data and biobank infrastructure (e.g., the Genome Center), episodic use of PM in healthcare, industry specialist and public education forums (e.g., PMNET Forum), and scientific research. Further development would require the creation and coordination of a unified policy and action plan involving all stakeholders.

In order for PM to be widely introduced in Latvia, the **development of PM should be one of the strategic goals in national policymaking documents**, and long-term cooperation and sustainable funding should be ensured for all stakeholders in the PM ecosystem.

Ensuring equitable, effective, and safe delivery of precision medicine services requires a coordinated national approach based on appropriate policy and legislation. Effective public and patient engagement will build and maintain trust and transparency about the ethical framework and legislation underpinning all aspects of service delivery and research, including ownership of clinical data and the informed consent process.

Learning from the experience of other countries (like Estonia), in the initial stages it is reasonable to **evaluate the implementation of the Precision Medicine pilot project** in one of the disease groups in which improvements in patient health outcomes are critically needed.

We call to establish a National Precision Medicine Ecosystem Coordination Group or Coalition involving all stakeholders, which would promote cooperation between various members of the ecosystem and promote the targeted development of PM in Latvia.

Tasks of the PM coordination group or coalition should include:

- Definition of a single overarching goal and determination of objectives and performance indicators
- Development of an action plan and/or road map
- Ensuring legal regulation
- Creating an appropriate environment for health data, registers, and digital technologies
- Examination of ethical issues
- Public education and patient involvement
- Promotion of cooperation and knowledge exchange between stakeholders
- Promotion of cooperation with industry and innovation
- Planning and provision of long-term financing (for both the public and private sector)

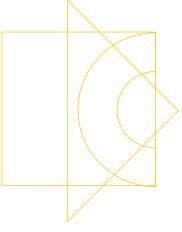
PM has the potential to significantly improve the quality of life and efficacy of healthcare for the population of Latvia. In addition, there is an opportunity to develop innovations and start-ups in the fields of new diagnostics, treatments, or data processing. The development and implementation of a unified policy and action plan, as well as the promotion of cooperation and knowledge exchange between all stakeholders, will help ensure the successful development of PM in Latvia.

Recommendations

Accurate medical information should be one of the strategical goals in national policymaking documents

Evaluate the implementation of the precision medicine pilot project

We invite the creation of a coordination group or coalition for the national precision medicine ecosystem



On Latvia's precision medicine ecosystem



AGNESE VAIULIENE
State Secretary
Ministry of Health of Latvia

I'd like to emphasize that precision medicine is an opportunity to use the funds allocated to health wisely and for the benefit of patients. But we must walk this path together with both experts and policymakers, therefore I commend and highly appreciate the initiative to create a common think tank. The Ministry of Health will continue to develop the personalized medicine approach by improving the diagnostics and creating the opportunity for more patients to receive personalized healthcare services and to introduce new, innovative solutions in state-paid healthcare to improve the patient experience and outcomes. We are working on several pilot projects in this area, which will lead to personalized therapy for breast cancer patients, diagnosis and treatment of cardiovascular diseases and Lynch syndrome. Precision medicine has already become a part of the Latvian healthcare system.



ILZE LORE
Deputy State Secretary
Ministry of Economics of Latvia

Precision medicine is not only an opportunity to improve public health, but also a significant development opportunity for the Latvian economy. Priority areas of the Ministry of Economics include biomedicine, medical technologies and pharmaceuticals as we are aware that investments in medicine, especially in precision medicine, can significantly improve the efficiency of treatment and the quality of life of citizens and opportunity to live longer and healthier lives, thus creating a strong and sustainable future for the entire country.



VALTS ABOLS
CEO at Children's Clinical
University Hospital

Precision medicine in pediatrics radically changes the process of treating children. This is especially important in children's oncology, where, by understanding the genetic structure of the tumor, the Children's Hospital has been trying to adapt more targeted and effective therapy for several years, reducing side effects and improving results. Children's Hospital is committed to taking the next steps in this field by creating a center for precision medicine. It will serve as an epicenter for research, education and the introduction of new technologies and treatments, with a special focus on oncology and rare diseases.



JANIS KLOVINS, Ph.D.
Professor, Head of
the Scientific Council,
Latvian Biomedical Research
and Study Centre

Several projects are currently being implemented, such as the Genome Reference of the Latvian population, in which the data processing platforms created would open the possibility for Latvia to become a significant player in the field of precision medicine. By successfully collaborating with other European countries, we are closer to the moment when the knowledge accumulated in research could be used to determine the risk of disease for every Latvian resident, thus promoting both disease prevention and optimal treatment.



ARVIDS IRMEJSDr. Med. Associate Professor
Riga Stradins University

Each year in Latvia, several hundreds of people get inherited cancer, which can be predicted, diagnosed much earlier or even prevented by performing a timely genetic testing that is not that expensive. In addition, the direct and indirect costs of treating cancer (incl. inability to work, disability, etc.) are increasing rapidly. By introducing personalized genetic screening for cancer risk, Latvia could become the first country in the world where such an innovative approach is implemented on a national scale and comprehensively optimizes oncological care.



ILZE AIZSILNIECE
President of the Latvian
Medical Association

The Latvian Medical Association believes that patient-oriented medicine is an important part of future healthcare. The 9th Latvian Doctors' Congress held in 2022 was dedicated to the advancement of patient-cetered precision medicine. Discussions about the future of precision medicine must continue.





INESE CAKSTINA-DZERVE Leading Researcher, Institute of Microbiology and Virology Riga Stradins University

Although many put an equal sign between "precision medicine" and "genomics or genome (genetic) testing", in reality, it is a much broader field. PM is a new approach to the treatment and prevention of diseases, which takes into account individual differences of each person (genes, cells, environment, lifestyle). Scientific literature contains quite a lot of data attesting to the benefits of the PM approach. In order to implement such an approach, all involved specialists (doctors, researchers, patient organizations, health insurance specialists, entrepreneurs, legislative and supervisory institutions) must work together as a single PM coalition team.



ERIKS MIKELSTEINS

NGO representative
a male survivor, co-author
of the public platform

ViriesuVeselibai.ly

Precision medicine means longer life expectancy – a very important factor for every member of society (almost 70 years of age for men and 80 years for women) – according to which we have been ranked far from the first places in Europe. Everyone, from the moment they are born, with the help of precision medicine and their parents, will have the opportunity to protect themselves during childhood, adolescence and at later ages. And we need to stand next to other countries where doctors, medical scientists and society-at-large, represented by NGOs, are aligned in their efforts to raise awareness of the importance of people's involvement in clinical research for human longevity and health skills.



AIJA GERINA, Ph.D.
Latvian Association
of Chemotherapists and
Oncologists Chair
of the Board

The goal of precision medicine in oncology is to provide precise cancer treatment to the patient at the right time and in the right dose, with fewer side effects and high therapeutic efficiency. This includes a precise diagnosis of cancer and a detailed study of the structure of the cancer cell. In oncology, the mechanism of action of innovative drugs is focused on biomarkers expressed by cancer cells – proteins, genes and their mutations. It is the revolution in defeating cancer, which has made a significant impact on the survival of cancer patients by prolonging it. The diagnosis of previously incurable and fatal cancer has become a chronic and manageable disease.



RAIVIS BREMSMITS
Director of the Latvian
Investment and
Development Agency

In the field of precision medicine, Latvia has an excellent research infrastructure and highly qualified scientists who create preconditions for the development of innovations and new companies in the field of biotechnology. Latvian companies and researchers are working on artificial intelligence solutions that can improve diagnosis, treatment and disease prediction. These technologies are in global demand because of their ability to significantly speed up diagnostic processes, for example, through image recognition in medical examinations and data analysis. Therefore, this sector has a high export potential both in research and other fields because precision medicine solutions are in global demand and can be easily adapted in many countries all over the world.



SANITA SINICA, Mg.sc. Board Member Latvian Alliance of Rare Diseases

Each person deserves an individualized approach to their treatment considering their genetics, which allows for the adjustment of treatment methods and medications. The only chance and hope for recovery of patients with rare diseases is the development of science. Precision medicine can provide a better quality of life for rare disease patients as well as improve health, extend life expectancy, and possibly even reduce the number of rare diseases. Every progress requires investment, work, sacrifice, and devotion. We stand ready to act to help science by helping ourselves and every member of society. Precision medicine must become a reality in the nearest future.



OLGA VALCINA
Board Member
The Association of Latvian
patient organizations
"Onkoalianse"

Precision medicine for patients means the chance to survive and defeat cancer. Modern, patient-oriented healthcare is inseparable from precision medicine. Precisely targeted therapy is still associated with complex and slow bureaucracy, insufficient access to testing and medicines, however, as patients we are always looking for the magic words "cancer is gone" so there is still a lot of work remaining to be done.





MARCIS LEJA, Ph.D,
Professor of Faculty of Medicine
University of Latvia,
Director of the Institute of Clinical
and Preventive Medicine at
the University of Latvia,
Full Member of the Latvian
Academy of Sciences

Personalized prevention and screening approaches are extremely attractive. Organized programs in the framework of which targeted residents are informed and trained, and invited to undertake preventive measures, guided by the data characterizing the specific individual, including previous examinations, ideally combining this information with genetic data, reveal the predisposition to a specific disease. Today we are only at the beginning of this journey. It is essential that there are high-quality and comprehensive data systems in place to use such data, but equally important is public trust in the healthcare system so that the society is ready to share this data. From now on, Latvia has every opportunity to take a leading role in these areas of precision medicine.



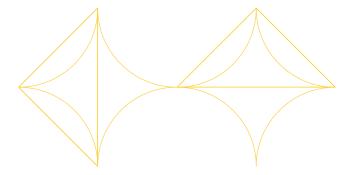
UNA RIEKSTINA, Ph.D.
Professor, the Faculty of
Medicine and Life Sciences
at the University of Latvia

Precision medicine is a medical approach that tailors treatment to the individual characteristics of each patient, including their genetic makeup, environment, and lifestyle. Advances in biotechnology have facilitated the identification of the molecular and genetic causes of many diseases, enabling the development of precisely targeted therapies. The coalition of Precision Medicine will unite Latvian researchers, doctors, business representatives as well as resources of the healthcare and medicine regulatory authorities to ensure that Latvian citizens have access to modern diagnostics and effective medicines.

References

- ¹ https://www.izm.gov.lv/lv/biomedicina-medicinas-tehnologijas-biofarmacija-un-biotehnologijas
- ² https://domnicalaser.lv/latvija-2040-cetri-nakotnes-scenariji/ "1.scenārijs. Baltijas tīģeris. Rīga ir kļuvusi par vienu no Eiropas veselības, medicīnas un farmācijas pakalpojumu, pētniecības, mācību un ražošanas centriem"
- ³ https://www.fda.gov/medical-devices/in-vitro-diagnostics/precision-medicine "Precision medicine, sometimes known as "personalized medicine" is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles.
- ⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AC%3A2015%3A421%3AFULL#ntr8-C 2015421EN.010 00201-E0008 "Precision (personalised medicine) refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention"
- ⁵ https://doi.org/10.1159/000501465
- ⁶ Dzau, V. J., Ginsburg, G. S., Van Nuys, K., Agus, D., & Goldman, D. (2015). Aligning incentives to fulfil the promise of personalized medicine. The Lancet, 385 (9982), 2118-2119
- ⁷ Jaskulski, S., Nuszbaum, C. and Michels, K.B., 2023. Components, prospects and challenges of personalized prevention. Frontiers in Public Health, 11, p.1075076. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9978387/
- ⁸ https://researchinestonia.eu/2023/06/20/international-study-shows-polygenic-risk-score-results-of-genetics-based -breast-cancer-precision-prevention/
- ⁹ Aboagye, Eric O., Tara D. Barwick, and Uwe Haberkorn. "Radiotheranostics in oncology: making precision medicine possible." CA: a cancer journal for clinicians 73, no. 3 (2023): 255-274. <u>Radiotheranostics in oncology: Making precision medicine possible Aboagye 2023 CA: A Cancer Journal for Clinicians Wiley Online Library</u>
- ¹⁰ Jaffee EM, Dang CV, Agus DB, et al. Future cancer research priorities in the USA: a Lancet Oncology commission. Lancet Oncol. 2017; 18(11): e653-e706. doi:10.1016/s1470-2045(17)30698-8
- ¹¹Precision treatment for metastatic non–small cell lung cancer: A conceptual overview | Cleveland Clinic Journal of Medicine (ccjm.org)
- ¹² Garrison Jr, L.P., Jiao, B. and Dabbous, O., 2021. Gene therapy may not be as expensive as people think: challenges in assessing the value of single and short-term therapies. Journal of managed care & specialty pharmacy, 27(5), pp.674-681. Gene therapy may not be as expensive as people think: challenges in assessing the value of single and short-term therapies PMC (nih.gov)

- ¹³ lesniegumi atzinuma par zāļu ārstniecisko un izmaksu efektivitāti saņemšanai (zva.gov.lv)
- ¹⁴ Cost Implications of Reactive Versus Prospective Testing for Dihydropyrimidine Dehydrogenase Deficiency in Pa tients With Colorectal Cancer: A Single-Institution Experience - Con Murphy, Stephen Byrne, Gul Ahmed, Andrew Kenny, James Gallagher, Harry Harvey, Eoin O'Farrell, Brian Bird, 2018 (sagepub.com)
- ¹⁵ https://www.efpia.eu/about-medicines/development-of-medicines/precision-medicine/#:~:text=Precision%20me dicine%20is%20based%20on,benefit%20from%20a%20specific%20treatment
- ¹⁶ https://nollvisioncancer.se/wp-content/uploads/2024/06/Report-Precisionsmedicin-Victri-2024_1.pdf
- ¹⁷ https://www.tai.ee/en/personalisedmedicine
- ¹⁸ https://strata.gov.lt/wp-content/uploads/2024/07/20240701_Personalizuotos-medicinos-vystymo-Lietuvoje-gali mybiu-studija.pdf
- ¹⁹ https://genomicmedicine.se/en/2022/09/19/successful-implementation-of-precision-medicine-at-a-national-level/
- https://www.eng.ngc.dk/about-the-danish-national-genome-center/national-strategy-for-personalised-medicine-2017-2020
- ²¹ Stenzinger, A., Moltzen, E.K., Winkler, E., Molnar-Gabor, F., Malek, N., Costescu, A., Jensen, B.N., Nowak, F., Pinto, C., Ottersen, O.P. and Schirmacher, P., 2023. Implementation of precision medicine in healthcare—A European perspective. Journal of Internal Medicine, 294(4), pp.437-454. https://onlinelibrary.wiley.com/doi/10.1111/joim.13698
- ²² Galvenie fakti par atsevišķām precīzijas medicīnas iniciatīvām Eiropā "top-down" un "bottom-up". NHS, Nacionālais veselības dienests; WGS, visa genoma sekvencēšana. Stenzingeret al., 2023. 294(4), 437.-454.lpp.
- ²³ https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00238-7/fulltext



AmCham speaks on behalf of more than 160 leading U.S. and international companies in Latvia. It is committed to fostering trade, investment, partnership and friendship between the U.S. and Latvia and serves as a business, knowledge, networking and policy forum. Among AmCham's priorities is the development of human capital in areas including preparing for the future of work and improving health outcomes of Latvia's society with the aim to increase and secure investments.

The AmCham Healthcare work group is an executive forum for organizations from across various industries. It brings together international experience and perspective aiming to improve the quality and access to healthcare, improve health outcomes, increase efficiency and drive innovation into Latvia's healthcare system.



