

PRECISEU

WORK PACKAGE 3 D3.3 Case Study Poland

IA Lithuania

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CONSORTIUM PARTNERS

	Name of the Entity	Acronym	Role	Country
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2	CATALUNYA	SALUT	BEN	ES
3	BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE	BSC-CNS	BEN	ES
		BIODN	DEN	
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7	ASOCIATIA DIGITAL INNOVATION ZONE	DIZNE	BEN	RO
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8	CLUSTERUL REGIONAL INOVATIV DE IMAGISTICA MOLECULARA SI STRUCTURALA NORD-EST (IMAGO-MOL)	IMAGO-MOL	BEN	RO
9	BIOTEHNOLOGICHEN I ZDRAVEN KLASTER	HLSCB	BEN	BG
10	STOLICHNA OBSHTINSKA AGENTSIA ZA	SIA	DEN	PC
10	PRIVATIZATSIA I INVESTITSII	SIA	DEIN	DG
11	CLUST ER INDUSTRIE DELLA SALUTE E DEL	CLUST ER	BEN	IT
12		DED	DEN	17
12		RER	BEN	11
13	ART-ER-SOCIETA CONSORTILE PER AZIONI	ARI-ER	BEN	
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16	VIESOJI ISTAIGA INOVACIJU AGENTURA	IA LITHUANIA	BEN	LT
17	BRG, BUSINESS REGION GOTEBORG AB	BRG	BEN	SE
18	EATRIS ERIC	EATRIS	BEN	NL
19	PLATAFORMA DE ORGANIZACIONES DE PACIENTES	POP	BEN	ES
20	AGENCIA PER A LA COMPETITIVITAT DE LA	ACCIO	BEN	ES
-		500711100	DEN	
21	IDRYMA TECHNOLOGIAS KAI EREVNAS	FORTH-ICS	BFN	EL
22	REGION OF CRETE	CRETE	BEN	EL
23	SAHLGRENSKA SCIENCE PARK AB	SSP	BEN	SE
24	RIVNE INTERREGIONAL MEDICAL CLUSTER	RIVNE	BEN	UA
25	ASTRAZENECA FARMACEUTICA SPAIN S.A.	ASTRAZENECA	BEN	ES

Tab. 1 The PRECISEU'S Consortium





WORK PACKAGES AND LEADERS

Work I	Packages Name	WP Leader
WP 1	Project Management and Coordination	Biocat
WP 2	Communication and Dissemination	NE RDA
WP 3	Interregional Collaboration and Partnership Bridging	IA Lithuania
WP 4	Use of Health Data	ART-ER
WP 5	Multistakeholder infrastructure to enable access to ATMP on large scale	BIO PRO
WP 6	Market and Patient Access	SSP
WP 7	Training and Cultural Change	HLSCB
WP 8	Adoption of PM innovations in the HealthCare System	SALUT
WP 9	Innovation Support Program	Biocat

Tab. 2 The PRECISEU'S Work Packages

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LIST OF ACRONYMS AND ABBREVIATIONS

Abbreviation	Description
ABM	Agencja Badań Medycznych, en. Medical Research Agency
Al	Artificial Intelligence
ATMP	Advanced Therapy Medicinal Product
ATMP-HE	Advances Therapy Medicinal Product – a Hospital Exemption
CRSC	Clinical Research Support Centre
EC	European Commission
EHR	Electronic Health Record
EMA	European Medicines Agency
EU	European Union
FDA	U.S. Food and Drug Administration
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GEP	Gender Equality Plan
GP	General Practitioner
IKP	Internetowe Konto Pacjenta, en. Patient Internet Account
INNOWO	Institute of Innovation and Responsible Development
MS	Member States
NCBR	National Centre for Research and Development
NFZ	Narodowy Fundusz Zdrowia, en. National Health Fund
OMICRON	Jagiellonian University Centre for Medical Genomics
PARP	Polish Agency for Enterprise Development
PESEL	a unique identifier that is assigned to each natural person
	residing in the country
PHC	Primary Healthcare
PM	Personalised Medicine
PPPs	Public-Private Partnerships
PRECISEU	Project "PeRsonalised medicine Empowerment Connecting
	Innovation ecoSystems across Europe"
RIV	Regional Innovation Valley
RNA	Ribonucleic Acid
UHC	Universal Health Coverage
URPL	The Office for registration of Medicinal Products, Medical
	Devices and Biocidal Products



EXECUTIVE SUMMARY

Europe ambitions to have the best talent working with the best companies, with deep-tech innovation creating breakthrough solutions across the continent and inspiring the world. The Regional Innovation Valleys (RIVs) aim to strengthen and better connect regional innovation players throughout Europe, including regions with lower innovation performance.

RIV initiatives will support Member States (MS) and regions in bridging the gaps and activating innovations in deep-tech for key priorities of the European Union (EU); directing funding to concrete interregional innovation projects — complementing large networks and consortia at the MS Level and placing Europe at the forefront of wellbeing and sustainable transition.

Europe's competitiveness relies largely on technology-based innovations in the health sector. Healthcare innovations represent a pillar of all EU policies and a cross-cutting priority, with fundamental importance to public authorities and local communities in terms of investment opportunities and the quality of life of the 448 million citizens of the European continent. And the most transformative commitment that the European Commission (EC), along with National and Regional Authorities, is acquiring toward healthcare is to channel huge efforts and funding towards Personalised Medicine (PM), which is on the backbone of several initiatives for building the European Health Union, and the ground test for the technology-driven transformation of the health care domain.

According to the European Council's conclusion on Personalised Medicine for patients, Personalised Medicine refers to "a medical model using the characterisation of individuals' phenotypes and genotypes 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."¹

PRECISEU envisions accelerating the integration of the PM paradigm across Europe, sustainably connecting regional innovation ecosystems, reducing the gap between regions, and facilitating patients' access to deep-tech innovations. In five years, we will have successfully improved the framework for the secondary use of health data and the development of ATMPs, supporting the access of PM technologies to the market and becoming a trusted player in the EC's strategy to empower PM at the regional level.

¹ Council of the European Union, Official Journal of the European Union, Council conclusions on personalised medicine for patients (2015/C 421/03). Available at: <u>https://op.europa.eu/en/publicationdetail/-/publication/f416ce37-a48c-11e5-b528-01aa75ed71a1/language-en</u>





INTRODUCTION TO THIS REPORT

The partners of PRECISEU identified the relevance of highlighting the challenges of an effective implementation of Personalised Medicine model across EU by aligning their actions to the events taking place during the Presidencies of the EU. At the moment of publication of this case study, Poland holds the presidency of the Council of the EU (for the second time) between 1 January 2025 and 30 June 2025. During this period the priorities of the Polish presidency are the following:²

- Defence and security
- Protection of people and borders
- Resistance to foreign interference and disinformation
- Ensuring security and freedom of business
- Energy transition
- Competitive and resilient agriculture
- Health security.

The PRECISEU consortium understands that their project contributes largely to Health security priority. The partners also highlight the underrepresentation of Health, Health innovation, Personalised Medicine, health Data and Advanced Therapies in the Polish presidency Program. The partners are also aware of the organisation of a High level event on Life Sciences (LifeSciences4EU) during the presidency and will make public the insights from this report with the event (May 2025), co-organised with Klaster Life Sciences Krakow. For this reason, and complying with the commitments of PRECISEU's Grant Agreement, the partners deliver this case study reviewing the capacities, assets, gaps and opportunities of Poland in this field, and have already engaged with Polish partners in the celebration of activities during this presidency.

² Polish Presidency Council of the European Union. Priorities, 2025. Available at: <u>https://polish-presidency.consilium.europa.eu/en/programme/priorities/</u>





1. Polish Ecosystem Overview

NATIONAL HEALTH SYSTEM

Poland's healthcare system is managed by the **National Health Fund (Narodowy Fundusz Zdrowia, NFZ)**, which ensures nearly universal health coverage (UHC) to all Polish citizens. Currently, more than 37 million people live in Poland and it's the ninth-largest country in Europe.³ The National Health Fund (NFZ) was established in 2003 and is primarily financed through social health insurance contributions, supplemented by government funds. The NFZ provides access to various health services, including primary care, specialist consultations, hospital treatments, and long-term care.⁴

In Poland, primary healthcare (PHC) is provided by general practitioners (GPs), who are often the first point of contact for patients. Secondary healthcare includes specialist services, typically accessed through referrals from primary care. Tertiary care involves highly specialized treatments, often provided in major hospitals and academic medical centers such as oncology centers and cardiovascular units.

In 2022, Poland spent approximately 6.7% of its GDP on healthcare, below the EU average of 9.9%. Around 34% of total health expenditure accounts for inpatient care and around 31%- for outpatient care. The rest is spent on pharmaceuticals, rehabilitation, and administrative services.

While 70-75% of healthcare costs are financed publicly, the remaining 25-30% comes from private out-of-pocket payments, mainly for pharmaceuticals and private consultations.⁵ Therefore, private healthcare also plays an important role in Polish healthcare ecosystem, especially for patients seeking faster or specialized services. According to a study conducted in 2016, nearly half of respondents declared use of both private and public health services. The main reason for private healthcare choice is caused by long waiting for public health care services.⁶

The country faces a shortage of healthcare professionals having only 3.4 doctors per 1,000 people, below the EU average of 4.1.⁷ This shortage escalates access issues, especially for specialized and tertiary care in rural areas. However, it is expected that this number will increase to 3.7 per 1,000 people by 2028.⁸ Challenges in the healthcare system include long waiting times for specialist appointments and surgeries, with non-urgent cases often delayed for months. Geographic disparities further limit access, with rural areas struggling to provide adequate tertiary care.

The Ministry of Health supervises healthcare regulations, with a focus on improving access to medical services, increasing healthcare efficiency, and modernizing the healthcare infrastructure. Personalized medicine is gaining more and more attention in Poland. It holds the potential to address inefficiencies within the current

at:

³ European Union, 2024. Poland Overview. Available at: <u>https://european-union.europa.eu/principles-countries-history/eu-countries/poland_en</u> ⁴ Eurofound, 2006. Doctors clash with the National Health Fund over healthcare agreement. Available <u>https://www.eurofound.europa.eu/en/resources/article/2006/doctors-clash-national-health-fund-over-healthcare-agreement</u>

⁵ OECD, 2023. Health at a Glance 2023: OECD Indicators, OECD Publishing, Paris. Available at: <u>https://doi.org/10.1787/7a7afb35-en</u>.

⁶ Using benefits and health insurance, 2016. Available at: <u>https://www.cbos.pl/SPISKOM.POL/2016/K_112_16.PDF</u>

⁷ State of Health in the EU Poland Country Health Profile 2023, 2023. Available at: <u>https://www.oecd.org/en/publications/poland-country-health-profile-2023_f597c810-en.html</u>

⁸ Economist Intelligence Unit, 2024. Healthcare report: Healthcare provision. Available at: <u>https://viewpoint.eiu.com/analysis/article/73995390</u>



system by providing more accurate diagnostics and treatments based on individual genetic and molecular profiles.

Demographic factors	Poland	EU		
Population size	37 654 247	446 735 291		
Share of population over age 65 (%)	19.1	21.1		
Fertility rate ¹ (2021)		1.5		
Socioeconomic factors				
GDP per capita (EUR PPP²)	28 044	35 219		
Relative poverty rate ³ (%)	13.7	16.5		
Unemployment rate (%)	2.9	6.2		

Fig. 1: Demographic and socioeconomic context in Poland, 2022 (source: State of Health in the EU Poland Country Health Profile 2023)9 1. Number of children born per woman aged 15-49. 2. Purchasing power parity (PPP) is defined as the rate of currency conversion that equalises the purchasing power of different currencies by eliminating the differences in price levels between countries. 3. Percentage of persons living with less than 60 % of median equivalised disposable income. Source: Eurostat Database.

HEALTH DATA LANDSCAPE

Polish government has taken steps to digitalize healthcare data with projects like **Electronic Health Record (EHR)** system and the **Patient Internet Account (Internetowe Konto Pacjenta, IKP)**. These systems allow patients to access their health information online, yet the health data infrastructure in Poland is still evolving.

Main challenges in Polish health data landscape concern data interoperability, integration, and protection of sensitive personal information. To fully unlock the prospects of personalized medicine, Poland must continue developing frameworks for the secure exchange of health data across medical institutions, researchers, and healthcare providers.

Poland is also actively involved participant in European Union initiatives promoting the use of big data and artificial intelligence (AI) in healthcare, which are key enablers of personalized medicine. After the COVID-19 pandemic, the focus on telemedicine increased and this has also accelerated the country's efforts to integrate digital health technologies.

LIFE SCIENCES

Poland's life sciences sector is growing, supported by the country's highly educated workforce and competitive research environment. The pharmaceutical industry is one of the most prominent within the life sciences sector, making Poland the 16th-largest pharmaceutical producer in the EU and employing more than 25 thousand people. Key domestic players in Polish pharmaceutical industry are **Polpharma** (privately owned company) and **Neuca** (largest local pharmaceutical distributor)¹⁰. While this industry has traditionally focused on developing generics, many pharmaceutical companies have started moving towards developing biologics. Meanwhile, biotech startups are evolving new technologies with a strong focus on treatments for cancer and autoimmune disease.

¹⁰ Economist Intelligence Unit, 2024. Healthcare report: Pharma and biotech. Available at: <u>https://viewpoint.eiu.com/analysis/article/103995393</u>



⁹ State of Health in the EU Poland Country Health Profile 2023, 2023. Available at: <u>https://www.oecd.org/en/publications/poland-country-health-profile-2023_f597c810-en.html</u>



Business in Polish life science sector is developing three major strategies: contract research, laboratory services and medical devices; innovative biotechnology products using molecular biology technologies; biosimilars development. Several Polish companies, such as **Celon Pharma** and **Molecure**, are involved in the development of innovative biological drugs, which play a crucial role in the advancement of personalized medicine.¹¹

Furthermore, the Polish government actively supports innovation in life sciences through various funding programs and R&D infrastructures such as **Medical Research Agency (Agencja Badań Medycznych, ABM)** and **The National Centre for Research and Development (NCBR)**. Public-private partnerships and collaborations with international stakeholders further strengthen the sector's capacity to contribute to global healthcare challenges.

CLUSTERS AND NETWORKS

- Klaster LifeScience Krakow focuses on innovation in life sciences bringing together companies, universities, research institutions, and public sector organizations. It's an EIT health hub with activities on Smart Health and on Active and Healthy Ageing.
- MedicalHub, Polish Cluster of Medical Technologies aim to collectively create conditions for conducting research as well as implementing and transferring knowledge in the field of medical technologies.
- **BioTechMed Cluster Mazovia** is a network of companies, science and research facilities, and business institutions, for whom the key condition for development is the introduction of new solutions into the economic practice.
- **PIKMED, Polish Innovative Medical Cluster** is an interregional organizational structure of the corporate relationship character, which operates within the medical and health protection branches.
- NTMed, Cluster of New Medical Technologies of the Warsaw University of Technology supports the development of innovation in the Polish medical devices and medical products sector.
- **MedCluster** is a nationwide medical cluster, which aims to develop innovative networks of cooperation that harness the potential of people, medical entities, enterprises, universities, research institutes and local self-governments units.

PROFESSIONAL ASSOCIATIONS AND REGULATION BODIES

- The Polish Chamber of Physicians and Dentists is the organizational body of the professional selfgovernment of physicians and dental practitioners. The chamber deals with all kinds of matters concerning the exercise of medicine and dentistry in Poland.
- The Polish Society of Human Genetics has more than 8,000 individuals including analysts, academicians, clinicians, research facility hone experts, hereditary advocates, and medical caretakers.
- The Polish Society of Oncology is the oldest and largest scientific society in the field of oncology in Poland. The society comprises more than 1,000 doctors, scientists and other people

¹¹ Labiotech, 2024. Eight biotechnology companies leading the charge in Poland. Available at: <u>https://www.labiotech.eu/best-biotech/biotechnology-companies-poland/</u>





representing various fields related to basic research, epidemiology, diagnosis and treatment of cancer are members of the Society.

• The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) regulates the approval and monitoring of drugs and medical devices, ensuring the safety and efficacy of new treatments.

ACADEMIA

- University of Warsaw has the Centre of New Technologies (CeNT UW), which is a leading hub for research in molecular biology and bioinformatics.
- Jagiellonian University in Kraków offers robust training programs in biomedical sciences and clinical research with its Center for Medical Genomics OMICRON.
- Warsaw Medical University offers specialized courses in personalized medicine, including training programs in clinical investigations and genetic diagnostics.
- Wroclaw Medical University has medical and scientific programs that touch personalized therapies, particularly in pharmacogenomics and bioinformatics.
- **Poznan University of Medical Sciences** runs programs in clinical research and translational medicine with a focus on advancing precision oncology.

RESEARCH CENTERS

- The International Institute of Molecular and Cell Biology focuses on RNA molecular and cell biology, which are the basis for creating innovative therapeutic and diagnostic methods.
- Nencki Institute of Experimental Biology pays the most attention to studies that can be directly translated to health protection and improving quality of life, including novel therapies and diagnostic methods in cancer, diabetes, neurodegenerative diseases, neurological disorders, and other diseases of modern civilization.
- Wroclaw Research Center EIT+ organizes interdisciplinary research in the fields of biotechnology, medical technologies, clean power generation, information and communication technology, nanotechnology and advanced materials.
- Clinical Research Support Centre (CRSC) is an interdepartmental university unit, which coordinates, supports and handles the implementation of non-commercial academic research, as well as the projects funded from a competition grant of the Medical Research Agency and other institutions financing the non-commercial clinical trials. CRSC also supports and coordinates commercial clinical research conducted by the University's partners.
- Sano Centre for Personalized Computational Medicine develops sophisticated computer methods for the prevention, diagnosis and assistance of the treatment of diseases.





2. Existing Legal Framework

PRIMARY USE OF HEALTH DATA

The primary use of health data in Poland is governed by a combination of national legislation and European Union regulations. The key documents include Act on the System of Information in Healthcare (Ustawa o systemie informacji wochronie zdrowia), General Data Protection Regulation (GDPR), and Act on Patients' Rights and the Patients' Rights Ombudsman (Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta). Act on the System of Information in Healthcare establishes the framework for collecting, processing, and sharing health information within the healthcare system. It mandates the digitalisation of medical records and outlines the responsibilities of healthcare providers in maintaining EHRs.¹² As a member of the European Union, Poland adheres to the GDPR, which sets comprehensive rules for processing personal data, including health information.¹³ Act on Patients' Rights and the Patients' Rights Ombudsman guarantees patients' rights concerning access to their medical records and the protection of their health data. Both GDPR and this act emphasise the confidentiality of patient information and the conditions under which it can be disclosed.¹⁴

The primary use of health data in Poland is significantly advanced through the digitalisation of various medical records and processes. Some records are fully digitalised, enhancing the efficiency and accuracy of healthcare delivery. While medical images and discharge reports are partially digitalised, ongoing efforts aim to achieve comprehensive digital integration across all healthcare facilities.¹⁵

The list below indicates the status of digital maturity of the healthcare system in Poland:

- patient summaries fully digitalised
- electronic prescriptions (ePrescription) fully digitalised
- electronic dispensations (eDispensing) fully digitalised
- medical images and image reports partially digitalised
- laboratory results fully digitalised
- discharge reports partially digitalised.

SECONDARY USE OF HEALTH DATA

The secondary use of health data refers to the processing of health information for purposes beyond direct patient care, such as research, public health planning, and policy development. In Poland, this practice is governed by both national legislation and European Union regulations. The **General Data Protection Regulation** (GDPR) ensures that any secondary use of personal health data adheres to strict data protection standards, emphasizing the importance of patient consent and data anonymization.

¹⁵ State of Health in the EU Poland Country Health Profile 2023, 2023. Available at: <u>https://www.oecd.org/en/publications/poland-country-health-profile-2023_f597c810-en.html</u>



¹² Ustawa o systemie informacji w ochronie zdrowia, 2023. Available at: <u>https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20111130657/U/D20110657Lj.pdf</u> ¹³ CEE Legal Matters. Data Protection Laws and Regulations in Poland, 2024. Available at: <u>https://ceelegalmatters.com/data-protection-2024/poland-data-protection-2024?</u>

¹⁴ Białas, Monika & Rzeźnicki, Adam & Borowski, Konrad & Timler, Dariusz. Legal Conditions of Patients' Access to Medical Records in Poland, 2023. Journal of HealthStudyandMedicine.2022.53-69.10.2478/jhsm-2022-0007.Availableat:https://www.researchgate.net/publication/371033511Legal Conditions of Patients%27Access to Medical Records in Polandatice



Despite the legal frameworks in place, Poland faces challenges in fully realising the potential of secondary health data use. Issues such as regulatory barriers, lack of proper infrastructure, and limited public awareness impede the effective reuse of health data. Building public trust is one of the crucial factors in overcoming these challenges, as societal acceptance is essential for the successful implementation of data-sharing initiatives.¹⁶ These initiatives are also the way of enhancing secondary use of health data in Poland. For example, the World Bank has collaborated with the Polish government to pilot integrated care models aimed at ensuring that diagnostic, therapeutic, and rehabilitation services are more patient centered. Ultimately, these actions should lead to improved healthcare outcomes.¹⁷

Categories of electronic data available for secondary use in Poland¹⁸:

- EHRs
- data impacting health, including social, environmental behavioural determinants of health partially available, comprehensive integration is not fully detailed
- relevant pathogen genomic data, impacting human health partially available
- health-related administrative data, including claims and reimbursement data
- human genetic, genomic and proteomic data partially available, not fully integrated
- person generated electronic health data, including medical devices, wellness applications or other digital health applications partially available
- identification data related to health professionals involved in the treatment of a natural person
- population wide health data registries (public health registries) partially available
- electronic health data from medical registries for specific diseases partially available
- electronic data from clinical trials partially available
- electronic health data from medical devices and from registries for medicinal products and medical devices partially available
- research cohorts, questionnaires and surveys related to health partially available
- electronic health data from biobanks and dedicated databases partially available
- electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health partially available.

PATIENTS' RIGHTS

Patients' rights in Poland are protected under the Act on the Rights of Patients and the Patients' Rights Ombudsman. The act ensures that patients are informed about their health status, treatment options, and the potential risks and benefits of medical procedures. Patients must be informed and provide explicit consent before undergoing any medical intervention, ensuring respect for their autonomy and decision-making capacity. The process involves clear communication between healthcare providers and patients, detailing the nature, purpose, and potential outcomes of the proposed treatments.¹⁹ There is also an **opt-in model** for

¹⁸ Ustawa o systemie informacji w ochronie zdrowia, 2023. Available at: <u>https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20111130657/U/D20110657Lj.pdf</u> ¹⁹ Ustawa o systemie informacji w ochronie zdrowia, 2023. Available at: <u>https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20111130657/U/D20110657Lj.pdf</u>



¹⁶ Open Data Institute. From concerns to consent: addressing the issue of trust and other challenges impairing secondary use of health data in Poland and beyond, 2024. Available at: <u>https://theodi.cdn.ngo/media/documents/20240106_Secondary_Use_of_Health_Data_in_Poland_FINAL.pdf</u>?

¹⁷ World Bank Group Integrated Health Care in Poland, 2018. Available at: <u>https://www.worldbank.org/en/country/poland/publication/integrated-health-care-in-</u>poland?



consent, meaning that patients must actively agree to participate in medical treatments or research studies.²⁰ This model highlights the importance of patient autonomy and informed decision-making, ensuring that individuals are fully aware of and agree to the use of their health data or participation in clinical trials.

ATMPs REGULATION

The regulation of Advanced Therapy Medicinal Products (ATMPs) in Poland is aligned with European Union standards, particularly Regulation (EC) No 1394/2007. This regulation provides a framework for the development, authorisation, and supervision of ATMPs, which include gene therapy, somatic cell therapy, and tissue-engineered products.²¹ Poland has implemented these regulations through national legislation, and the Polish regulatory system also includes provisions for hospital exemptions (ATMP-HE), allowing the use of experimental ATMPs for patients with unmet medical needs under specific conditions.²² While ATMP-HE products can represent a final hope for patients lacking other effective treatment options, they also transfer the risk burden to the patient, as these products are used without comprehensive oversight and responsibility. There are discussions that, under current law (*de lege lata*), the use of an advanced therapy medicinal product under a hospital exemption should be considered a therapeutic experiment, subject to the same limitations and regulations that govern such experiments.²³

3. Innovation Agenda in the Field

OVERVIEW OF NATIONAL AND REGIONAL INNOVATION AGENDAS

Poland's innovation agenda in personalised medicine is supported at both the national and regional levels, with a strong focus on digital health and health data. The Polish Coalition for Personalised Medicine, established in 2015, plays a pivotal role in advancing systemic and legislative changes as well as supporting education to foster innovation in this field.²⁴

Initiatives such as the P4Health Project, funded under Horizon Europe, aim to develop and implement diagnostic and therapeutic solutions essential for advancing personalised medicine at the national level. The project will last for 6 years, and it seeks to improve access to innovative therapies. By integrating molecular diagnostics and precision medicine into routine clinical practice, the cost of healthcare should be reduced.²⁵

²⁵ Lukasiewicz Research Network. 'P4Health Project: Developing Breakthrough Implementations in Precision Medicine.', 2024. Available at: https://port.lukasiewicz.gov.pl/en/lukasiewicz-port-develops-breakthrough-implementations-in-precision-medicine/



²⁰ Be law. Who is the Patient Ombudsman? Available at: <u>https://www.belaw.pl/en/who-is-the-patient-ombudsman/</u>

 ²¹ European Union. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance). Available at: https://eur-lex.europa.eu/eli/reg/2007/1394/oj/eng
 ²² Pachocki J, Verter F. Polish regulatory system regarding ATMP hospital exemptions. Front Immunol. 2024;15:1379134. Published 2024 May 13. doi:10.3389/fimmu.2024.1379134

²³ "The Application of the Advanced Therapeutic Medicinal Product – Hospital Exemption and the Therapeutic Experiment". 2024. *Diametros* 21 (81): 66-79. <u>https://doi.org/10.33392/diam.1930</u>.

²⁴ Medycyna Personalizowana, 2024. Available at: <u>https://www.medycynapersonalizowana.com/</u>



CURRENT INFRASTRUCTURE AND INITIATIVES

- The Medical Research Agency (ABM) is a state agency responsible for the development of research in the field of medical sciences and health sciences. The Agency is implementing one of the first public grant programs with funding for non-commercial clinical trials in the country. It has allocated over PLN 500 million to digitize clinical trials across 18 units in Poland. The main goal of developing non-commercial clinical trials is to search for new treatment methods in the most pressing areas of medicine: oncology, cardiology, and rare diseases as these areas often remain outside the interest of private companies. The Agency also supports the development of population and epidemiological studies, which will define, for example, the reasons for the differences in the incidence of specific diseases or mortality rates due to selected diseases in individual regions of Poland.²⁶
- Polish School of Molecular Biology in Practice is one of INNOWO's, The Institute of Innovation and Responsible Development, initiatives organised in collaboration with the Polish Coalition of Personalised Medicine. Part of the school activities are workshops, which aim to familiarise oncologists with the basics of molecular biology and genetics, as well as the application of this knowledge in clinical practice. The future of oncology is primarily precision medicine, and its integral part will be advanced molecular diagnostics based on the latest scientific achievements in the field of molecular biology of tumours.²⁷
- National Centre for Research and Development (NCBR) has led a project 'Polish Reference Genome for Genomic Diagnostics and Personalised Medicine'. The main goal of the project was to create a reference database of the Polish Caucasian subpopulation for use in diagnostic processes and in personalised medicine research. The main tasks included collecting and presenting genomic data characterizing a healthy, long-lived Pole. This goal was fully achieved- a tested database was created, based on the complete genomes of 126 healthy, long-lived (90+) Poles, containing a rich set of clinical and biochemical data. Nearly 22 million sequence variants were detected and placed in the genomic database, of which approximately 24% were new variants.²⁸

MAIN PRIORITIES AND BARRIERS

Main Priorities of Innovation Agenda:

- Expanding access to molecular diagnostics and genetic testing, particularly in oncology.
- Enhancing the integration of health data systems, including electronic health records (EHR) and secure data-sharing.
- Training healthcare professionals in precision medicine methodologies.
- Facilitating public-private partnerships to accelerate commercialization of new technologies.

²⁸ NCBR. 'Polish Reference Genome for Genomic Diagnostics and Personalized Medicine', 2024. Available at: <u>https://www.gov.pl/web/ncbr-en/polish-reference-genome-for-genomic-diagnostics-and-personalized-medicine</u>



²⁶ Medical Research Agency. 'Poland Joins League of World Leaders in Digital Medicine', 2024. Available at: <u>https://abm.gov.pl/</u>

²⁷ Innowo. 'Projects in the Area of Health', 2024. Available at: HYPERLINK "https://www.innowo.org/en/projekty-w-obszarze-zdrowia" https://www.innowo.org/en/projekty-w-obszarze-zdrowia



• Educating politicians and citizens about personalised on a large scale (healthcare systems) and an individual scale (the patient-doctor relationship etc.).²⁹

Main Barriers of Innovation Agenda:

- Health data systems across institutions often lack compatibility, which hinders efficient data exchange.
- Legislative frameworks for personalised medicine and digital health solutions are still evolving, adding to regulatory complexity.
- Although funding has increased, scaling innovative projects across the healthcare system requires sustained investment.
- The adoption of advanced diagnostic tools is limited by a shortage of trained professionals in genomics and bioinformatics.
- Limited understanding of personalised medicine among patients can slow its acceptance and integration.³⁰

STATE OF IMPLEMENTATION

Personalised medicine in Poland has made significant strides but is still in the early stages of widespread implementation. Genetic testing rates have surged, particularly for oncology patients, with a threefold increase between 2018 and 2019, reflecting the positive impact of new funding models.³¹ Despite these advancements, integrating personalised medicine into routine care remains a work in progress, with regional disparities in access posing a major challenge. Digital health initiatives, such as digitising clinical trials, improving health data collection and sharing, and expanding the use of electronic prescriptions (e-recepta), are central to Poland's innovation agenda. However, overcoming barriers like data security and interoperability is crucial to fully realising this agenda's potential. In Poland, as in many other countries, certain medications require a prescription (recepta), which is now primarily electronic. Patients receive their e-recepta via SMS or email and can fill it at pharmacies using their PESEL number or passport number if they do not have a PESEL.³²

 ³⁰ MDPI. 'Barriers and Facilitators to the Implementation of Personalized Medicine Across Europe', 2023. Available at: https://www.mdpi.com/2075-4426/13/2/203
 ³¹ Mela A, Rdzanek E, Tysarowski A, Sakowicz M, Jaroszyński J, Furtak-Niczyporuk M, Żurek G, Poniatowski ŁA, Jagielska B. The impact of changing the funding model for genetic diagnostics and improved access to personalized medicine in oncology, 2023. Available at: https://pubmed.ncbi.nlm.nih.gov/36437684/
 ³² University of Warsaw, Welcome Point. Healthcare in Poland, 2024. Available at: https://welcome.uw.edu.pl/healthcare-in-poland/



²⁹ Medical Science Pulse. 'Personalized Medicine – Challenge for Healthcare Systems in Central and Eastern Europe', 2021. Available at: https://medicalsciencepulse.com/article/152648/en





Fig. 2: e-Prescription. Architecture, 2024 (source: https://pentacomp.net/products/health-cloud/integration-with-p1-systems-e-prescription-connector)

4. SWOT Analysis

STRENGTHS	WEAKNESSES	
 Growing research infrastructure, e.g. Regional Centres for Digital Medicine. Improving education through training programs like the Polish School of Molecular Biology in Practice. Government support through the Polish Medical Research Agency (ABM). Involvement in EU initiatives: Horizon Europe, Regions4PerMed, P4Health. Expanding access to molecular diagnostics: revised funding models for 	 Shortage of Healthcare Professionals: only 3.4 doctors per 1,000 people, leading to challenges in providing adequate access to specialised care, particularly in rural areas. Data interoperability issues: fragmented health data limit the seamless exchange of information, hindering large-scale implementation of personalised medicine. 	





genetic testing have significantly increased access, especially for oncology patients.

- Digital health and technological advancements: growing eHealth infrastructure, including electronic prescriptions (e-Recepta), digitised clinical trials, and the use of artificial intelligence supports the integration of personalised medicine into routine care.
- Funding gaps: while government funding has increased, sustainable long-term investment remains insufficient.
- Knowledge gaps and limited public awareness: there is a need for more education and training for healthcare professionals to effectively utilise PM approaches. Also, patients lack sufficient knowledge about the benefits and applications of personalised medicine.
- Regulatory and ethical challenges: data privacy issues slow the adoption of personalised approaches.

OPPORTUNITIES

- EU collaboration: partnerships with initiatives like EIT Health and countries leading in personalised medicine (e.g., Germany, France, Finland) can enhance knowledge transfer and funding opportunities.
- More Public-Private Partnerships (PPPs): increased collaboration between public institutions and private companies could drive innovation and implementation of PM solutions.
- Technological advancements and Al integration: continued advancements in genomics, biotechnology, and data science offer new possibilities for precision and predictive diagnostics and treatments.
- Patient-centric innovations: expanding telemedicine and digital health tools can enhance patient access to personalised care, especially in remote areas.
- Focus on rare diseases: collaborating on cross-border rare disease registries

THREATS

- Brain-drain: the emigration of healthcare professionals to higherpaying EU countries exacerbates workforce shortages.
- Economic constraints: rising production costs, transportation challenges, and supply chain disruptions as well as limited national healthcare spending could restrict the availability of personalised medicine treatments.
- Data privacy concerns: public concerns about the use of health data for research purposes could undermine trust in personalised medicine programs.
- Regulatory delays: inconsistent regulations and lack of adequate investment incentives can pose significant barriers to the development and implementation of PM.
- Competition with more advanced EU regions: countries with more established personalised medicine ecosystems may attract more





 can improve diagnostics and treatment for underrepresented patient groups.
 Pharmacogenomics development: scaling pharmacogenomic applications can optimise drug efficacy and reduce adverse reactions, attracting international R&D partnerships and investment. investment and talent, leaving Poland behind.

5. Transferable Good Practices

REGIONAL CENTRES FOR DIGITAL MEDICINE

The **Regional Centres for Digital Medicine** in Poland is a groundbreaking initiative aimed at integrating digital technologies into clinical research and personalised medicine. The Centres have been established with funding from the Polish Medical Research Agency (ABM), and they are strategically located across 18 regions to enable secure and efficient health data collection. With over 500 million PLN allocated to this project, the centres focus on thoroughly collecting and analysing diverse health data, including molecular diagnostics, clinical research findings, and disease progression records. The goal of this initiative is to create a robust infrastructure that facilitates comprehensive data-driven patient care while maintaining high standards of data privacy.

The Regional Centres for Digital Medicine are instrumental in enabling advanced data analytics, supporting the development of innovative therapies, and improving patient outcomes. By centralising and digitising health data, these centres enhance the capacity to conduct large-scale clinical studies, paving the way for breakthroughs in precision medicine. The initiative also emphasises collaboration among healthcare providers, researchers, and technology developers. Moreover, the centres aim to reduce disparities in healthcare access by offering standardised and inclusive platforms for health data utilisation across Poland.³³³⁴

The regional centre initiative provides a replicable model for other regions seeking to integrate digital health and data management into their healthcare ecosystems. By linking data from diverse sources and employing advanced analytics, it should help to bridge the gap between traditional and personalised medicine.

POLISH SCHOOL OF MOLECULAR BIOLOGY IN PRACTICE

Organised by Innowo and the Polish Coalition for Personalised Medicine, the **Polish School of Molecular Biology in Practice (Polska Szkoła Biologii Molekularnej w Praktyce)** is an innovative initiative aimed at advancing the adoption of personalised medicine in Poland. The main goal of the program is to equip healthcare professionals, particularly oncologists, with foundational knowledge in molecular biology and genetics. The training curriculum emphasizes the practical application of this knowledge in molecular

³⁴ Regions4PerMed Project. "Poland's Efforts in Advancing Digital Medicine", 2024. Available at: <u>https://www.regions4permed.eu/</u>



³³ Polish Medical Research Agency. "Poland Joins League of World Leaders in Digital Medicine", 2024. Available at: <u>https://abm.gov.pl/</u>



diagnostics and clinical practice, ensuring that medical professionals are better prepared to integrate personalised approaches into patient care.

The initiative contributes to Poland's broader goals of improving cancer diagnostics and treatment outcomes by fostering expertise in precision oncology. Workshops under the program provide hands-on experience with cutting-edge diagnostic techniques, highlighting the role of molecular diagnostics in understanding tumour biology and adjusting treatments to individual patients. The initiative also aligns with the growing emphasis on precision medicine as a cornerstone of modern healthcare, particularly in oncology, where molecular diagnostics are becoming essential to clinical decision-making. The program highlights Poland's commitment to translating research into clinical practice and fostering a highly skilled workforce to advance the implementation of personalised medicine. Such professional development initiatives could serve as a transferable model for enhancing workforce capabilities in other regions.^{35,36}

NATIONAL GENOME AND MOLECULAR DIAGNOSTICS INITIATIVES

The Polish Reference Genome for Genomic Diagnostics is a project focused on creating a robust genomic infrastructure to support personalised treatments. A pivotal project in this domain was the Polish Reference Genome Project (2013–2016), which aimed to establish a comprehensive genomic database of Poland's population. The main goal of the latter project was to create a reference database of the Polish Caucasian subpopulation for use in diagnostic processes and in research in the field of personalised medicine. The collected genomic data characterizes a healthy, long-lived Pole.³⁷

As the funding for molecular diagnostics, particularly in oncology, increased, more genomic data was integrated into clinical practice. Between 2017 and 2019, Poland witnessed a significant rise in genetic testing for cancer patients, associated with reforms in funding models by the National Health Fund (NFZ). These changes tripled the availability of genetic testing, enabling more patients to exploit precision oncology treatments.³⁸

E-PRESCRIPTIONS (E-RECEPTA)

Poland has made significant progress in digital health, with initiatives like **e-prescriptions (e-Recepta)** leading the way in modernising the healthcare system. Introduced in 2019 as part of a broader eHealth transformation, the e-prescription system enables physicians to issue prescriptions electronically, improving efficiency and reducing errors. Patients can access their prescriptions through SMS, email, or a Patient Internet Account (Internetowe Konto Pacjenta, IKP), eliminating the need for physical documents. To fill a prescription, patients provide a unique access code along with their PESEL (national ID) number, shortening the process.³⁹

The e-prescription system has seen widespread adoption, significantly reducing paperwork and increasing accuracy. It facilitates monitoring of medication usage, allowing healthcare providers to track patient compliance and, more importantly, flag potential drug interactions. By digitising prescriptions, Poland has

³⁵ Innowo. "Projects in the Area of Health", 2024. Available at: <u>https://www.innowo.org/en/projekty-w-obszarze-zdrowia</u>

³⁶ Polish Coalition for Personalized Medicine. "About Us", 2024. Available at: <u>https://www.medycynapersonalizowana.com/</u>

³⁷ National Centre for Research and Development (NCBR). "Polish Reference Genome for Genomic Diagnostics and Personalized Medicine", 2024. Available at: <u>https://www.gov.pl/web/ncbr-en/polish-reference-genome-for-genomic-diagnostics-and-personalized-medicine</u>

³⁸ Tandfonline. "The Impact of Changing the Funding Model for Genetic Diagnostics and Improved Access to Personalized Medicine in Oncology." Available at: <u>https://www.tandfonline.com/doi/full/10.1080/14737167.2023.2140139</u>

³⁹ Polish Ministry of Health. "E-Prescriptions (e-Recepta)", 2024. Available at: <u>https://www.gov.pl/web/zdrowie</u>



aligned its healthcare practices with EU standards and reduced administrative burdens on both patients and doctors.⁴⁰

DATA ACCESSIBILITY AND FUNDING MODELS

Data accessibility is becoming a key enabler of personalised medicine, with initiatives focused on ensuring that patients and healthcare providers have efficient access to critical health information. The **Patient Internet Account (Internetowe Konto Pacjenta, IKP)** provides a central platform for patients to view their medical history, prescriptions, and referrals digitally, thereby empowering them to make informed decisions about their healthcare. Efforts to enhance the digitalisation of health records are gradually improving the availability and consistency of patient data, thus facilitating more accurate diagnostics and personalised treatment planning.⁴¹

The National Health Fund (NFZ) has evolved funding models by prioritising covering the costs of critical services such as genetic testing. Between 2017 and 2019, these reforms significantly increased the availability of genetic diagnostics, particularly for cancer patients, highlighting the substantial benefits of targeted funding strategies. Furthermore, Poland's participation in **Horizon Europe** projects and other EU-funded initiatives ensures additional resources for the development of precision medicine, allowing the country to remain competitive in healthcare innovation. These external funds complement national efforts, supporting both research and clinical applications.^{42,43}

Despite progress, challenges remain in ensuring equal access to these advances, especially for rural and underserved populations. Addressing the interoperability of healthcare systems and promoting closer public-private cooperation are essential next steps. Continued investment in infrastructure and robust policy frameworks will be crucial to increase data availability and funding mechanisms to fully exploit the potential of personalized medicine in Poland.

6. Good Practices Related to Gender Diversity and Inclusiveness

WOMEN IN STEM INITIATIVES

Poland has made significant efforts to promote gender diversity and encourage women's participation in science, technology, engineering, and mathematics (STEM). The **Perspektywy Education Foundation** is at the forefront, offering programs and scholarships aimed at empowering women in STEM fields, including healthcare and biotechnology. Their initiatives are designed to reduce barriers for women entering traditionally male-dominated fields, fostering a more diverse and inclusive workforce.⁴⁴ One flagship initiative

⁴⁰ Welcome Center, University of Warsaw. "Healthcare in Poland- E-Prescriptions", 2024. Available at: <u>https://welcome.uw.edu.pl/healthcare-in-poland/</u> ⁴¹ Polish Ministry of Health. "Patient Internet Account (IKP)." Available at: <u>https://pacjent.gov.pl/</u>

⁴² Tandfonline. "The Impact of Changing the Funding Model for Genetic Diagnostics and Improved Access to Personalized Medicine in Oncology", 2014. Available at: <u>https://www.tandfonline.com/doi/full/10.1080/14737167.2023.2140139</u>

⁴³ Horizon Europe. "Personalized Medicine Projects." Available at: <u>https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home</u>

⁴⁴ Perspektywy Education Foundation. "About Us", 2024. Available at: <u>https://womenintech.perspektywy.org/en/about-us/</u>



by Perspektywy Education Foundation is the **"Women in Tech Summit"**, which is one of Europe's largest gatherings of women in technology. The event provides networking opportunities, workshops, and even mentorship tailored to empower female students and professionals.⁴⁵ By focusing on areas like bioinformatics, genomics, and data science, these programs directly contribute to the development of personalised medicine.

WOMEN ENTREPRENEURS IN HEALTHCARE

Poland has implemented several initiatives to support women entrepreneurs in the healthcare sector, setting standards for gender diversity and inclusiveness. The Polish government actively promotes female entrepreneurship through various programs and grants. For instance, the **Polish Agency for Enterprise Development (PARP)** offers funding and resources specifically aimed at women-led startups. Additionally, Poland fosters an inclusive entrepreneurial environment through numerous networking and promotional campaigns. Events such as the **"Equality of labour market opportunities for men and women"** and **"Have it your own way – entrepreneurship"** campaigns and various entrepreneurship contests highlight successful women entrepreneurs, challenging traditional gender stereotypes.⁴⁶ Finally, initiatives like the **"Success is ME"** program, in collaboration with the **Foundation of Success Written with Lipstick**, provide training and mentorship to women.⁴⁷ These efforts not only empower women but also create a more balanced and diverse healthcare business ecosystem.

GENDER EQUALITY IN EDUCATION

Under Horizon Europe, the European Commission has introduced a **Gender Equality Plan (GEP)** eligibility criterion, which mandates that organisations applying for funding must have a GEP in place. This policy is designed to eliminate gender inequality and intersecting socio-economic disparities within research and innovation systems. In Poland, leading institutions like Warsaw University and Jagiellonian University have taken this initiative up, implementing comprehensive GEPs that serve as exemplary models. Warsaw University has integrated gender equality into its strategic planning, ensuring that gender balance is maintained in leadership roles and decision-making processes. This approach not only promotes a more inclusive academic environment but also enhances the quality of research and education by incorporating diverse perspectives. Jagiellonian University has also made significant strides in fostering gender equality through its GEP. The university has established a new Department of Safety, Security and Equal Treatment, which, among other responsibilities, is also responsible for gender equality. The department is working on the preparation of Equity Policy and Anti-discrimination Procedure and associated actions. By raising awareness and conducting regular training sessions on gender sensitivity and inclusivity, Jagiellonian University ensures that all members of its academic community are aware of and committed to gender equality principles.⁴⁸

⁴⁵ Perspektywy Education Foundation. "Summit", 2024. Available at: <u>https://womenintech.perspektywy.org/en/perspektywy-women-in-tech-summit-en/</u>

⁴⁶ SheAtWork. "Empowering Women Entrepreneurship: Unveiling Poland's Support Ecosystem", 2023. Available at: <u>https://sheatwork.com/empowering-women-entrepreneurship-unveiling-polands-support-ecosystem/</u>

⁴⁷ Resistire. "Supporting women in Poland through the 'Success is ME' programme", 2021. Available at: <u>https://resistire-project.eu/better-stories/supporting-women-in-poland/</u>

⁴⁸ European Union. Horizon Europe guidance on gender equality plans, 2021. Available at: <u>https://op.europa.eu/en/publication-detail/-/publication/ffcb06c3-200a-11ec-bd8e-01aa75ed71a1</u>?



7. Potential Synergies with Other EU Regions

EXISTING MULTI-REGIONAL PROJECTS AND INITIATIVES

Program, project	Countries	Focus Areas	Focus activities and outcomes
P4Health ⁴⁹	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Poland, Portugal, Spain, Sweden	Predictive, Preventive, Personalised, and Participatory healthcare	P4Health aims to develop and implement solutions essential for personalised medicine, including new diagnostic methods and more affordable therapies. The outcomes include advancements in personalised healthcare technologies and improved patient care through innovative diagnostic and therapeutic methods.
Regions4PerMed	Germany, Italy, Poland, Spain	Interregional coordination for personalised health	Regions4PerMed focuses on facilitating the adoption of personalised health by coordinating regional and national stakeholders. The project includes strategic area conferences, workshops, and a final conference to increase stakeholder involvement. Outcomes include enhanced cooperation among regions, better integration of personalised health practices, and alignment with European health strategies.
EIT Health ⁵¹	EU member states, Israel, Switzerland, UK	Health innovation and entrepreneurship	Key activities include the Transformative Health Instrument Call, which provides funding for high-potential healthcare startups, and the Deep Tech Venture Builder Programme. Outcomes include the development and commercialization of innovative healthcare solutions, improved healthcare delivery. and

⁴⁹ Sagner M, McNeil A, Puska P, et al. The P4 Health Spectrum - A Predictive, Preventive, Personalized and Participatory Continuum for Promoting Healthspan. Prog Cardiovasc Dis. 2017;59(5):506-521. Available at: https://indico.cern.ch/event/679940/attachments/1570151/2476483/P4-Health-Spectrum-2017.pdf ⁵⁰ Regions4PerMed. Rationale of the Project, 2024. Available at: <u>https://www.regions4permed.eu/project/</u>

⁵¹ EIT Health, 2024. Available at: <u>https://eithealth.eu/</u>





			strengthened European healthcare systems
EURORDIS ⁵²	74 countries, primarily in Europe	Rare diseases advocacy and support	EURORDIS advocates for people living with rare diseases, providing training and education through the EURORDIS Open Academy, and gathering patient insights via the Rare Barometer Programme. Key initiatives include Rare Disease Day, the EURORDIS Black Pearl Awards, and the European Conference on Rare Diseases and Orphan Products. Outcomes include increased awareness, improved policies, and enhanced support for rare disease patients.
Council of European BioRegions	45 health innovation ecosystems across Europe. Some polish clusters are active in this EU-wide network.	Key interests in Digitalisation, Biomanufacturing , policy positioning	45 subscription members and hundreds of cluster partners worldwide, collectively supporting a vast network of SMEs, universities, and research centers working Several active projects fostering personalised medicine
ScanBalt	Region with Nordic and Baltic countries connecting more than 3000 companies, 50 health care clusters and networks, 75 health care sector science parks and 60 universities active. It includes Polish partners active in the network.	Think Tank and Accelerator in life sciences and bioeconomy,	ScanBalt is an innovation network that brings together academic and industrial research, university hospitals and non-university research institutions, study centres and highly specialised suppliers in the pharmaceutical, biotechnology and medical technology sectors from different European countries and regions.

MAIN AREAS FOR FUTURE DEVELOPMENT AND COLLABORATION

• **Digital Health and Health Data:** Poland's Regional Centres for Digital Medicine could align with flagship digital health initiatives in countries like Lithuania⁵³ and Estonia⁵⁴ (e.g., their advanced eHealth and data-sharing platforms), Denmark (e.g., their National Genome Centre)⁵⁵ and

⁵⁵ Nationalt Genom Center. About the Danish National Genome Center, 2024. Available at: <u>https://www.eng.ngc.dk/about-the-danish-national-genome-center</u>



⁵² EURORDIS, 2024. Available at: <u>https://www.eurordis.org/</u>

⁵³ esveikata.lt. Apie ESPBI IS, 2023. Available at: <u>https://www.esveikata.lt/apie-espbi</u>

⁵⁴ e-Estonia. Enter e-Estonia: digital health, 2020. Available at: <u>https://e-estonia.com/enter-e-estonia-digital-health/</u>



Finland (e.g., Findata)⁵⁶. Also, Germany's investment in telemedicine and health apps under the Digital Healthcare Act (DVG)⁵⁷ could inspire Poland's integration of digital tools into personalised medicine.

- **Molecular Diagnostics and Genomic Research**: programs such as the Polish Reference Genome Project could find synergies with projects like the 100,000 Genomes Project in the UK⁵⁸ or France's Plan France Médecine Génomique 2025⁵⁹. Poland could partner with international research institutions to explore new biomarkers, genetic profiles, and treatment modalities. These collaborative genomic research initiatives would allow for pooled data and resources, accelerating progress in personalised therapies.
- **Regulatory Frameworks**: developing unified standards for health data usage and is crucial. Poland's regulatory bodies such as the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, URPL)⁶⁰ could work with European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) to harmonise regulatory standards.
- Public-Private Partnerships (PPPs): Poland could participate in global healthcare consortia and innovation hubs that bring together public institutions, private companies, and academic researchers. Additionally, Poland could seek partnerships with multinational pharmaceutical companies and biotech firms to co-develop and commercialise new treatments. Furthermore, Poland could enhance its engagement in international PPPs by actively participating in global health and innovation forums.⁶¹

⁶¹ European Council on Foreign Relations. Empowering Poland: The role of international partnerships, 2024. Available at: <u>https://ecfr.eu/publication/empowering-poland-the-role-of-international-partnerships/</u>



⁵⁶ Findata, 2025. Available at: https://findata.fi/en/about-findata/

⁵⁷ Federal Ministry of Health. Driving the digital transformation of Germany's healthcare system for the good of patients, 2020. Available at: <u>https://www.bundesgesundheitsministerium.de/en/digital-healthcare-act.html</u>

⁵⁸ Genomics UK. 100,000 Genomes Project, 2024. Available at: https://www.genomicsengland.co.uk/initiatives/100000-genomes-project

 <sup>59
 2025</sup> French
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⁶⁰ Gov.pl. Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, 2024. Available at: <u>https://www.gov.pl/web/urpl/struktura-urzedu2</u>



8. Conclusions

POSITIVE DEVELOPMENTS

- Poland has significant advancements in digital health, genomic research, precision oncology, and pharmacogenomics.
- The country is well-positioned to contribute to and benefit from collaborative EU initiatives.
- Poland already has synergies with other countries in addressing rare diseases, leveraging AI, and standardising data usage and ethical frameworks.

GAPS AND CHALLENGES

- Healthcare system issues: long waiting times, shortage of specialists, and underfunding in the healthcare system.
- Regulatory and ethical concerns, including data privacy issues.
- Knowledge gaps among healthcare professionals in genomics and bioinformatics.
- Low public awareness of the benefits of personalised medicine.

IMPROVEMENT OPPORTUNITIES

- Strengthen partnerships with EU leaders to share expertise and resources.
- Invest in digital infrastructure by prioritizing interoperability of health data systems and expanding Aldriven healthcare projects.
- Invest in training programs for genomics and bioinformatics for healthcare professionals.
- Raise public awareness through education campaigns to inform patients and providers about the benefits of personalised medicine.
- Focus on rare diseases by collaborating with EU networks to address rare diseases, leveraging Poland's growing expertise in genomics.

