



PRECISEU

WORK PACKAGE 6

D6.1 Cross Regional Report

Sahlgrenska Science Park

30/09/2025



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4	BIORN CLUSTER MANAGEMENT GMBH	BIORN	BEN	DE
5	BIOPRO BADEN-WUERTTEMBERG GMBH	BIOPRO	BEN	DE
6	AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST	NE RDA	BEN	RO
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15	BIOVIA (former MEDVIA)	BIOVIA	BEN	BE
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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 EMPRESA	ACCIO	BEN	ES
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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 partners



WORK PACKAGES AND LEADERS

Work 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

Acronym	Meaning
ADA-SCID	Adenosine Deaminase Severe Combined Immunodeficiency
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AI	Artificial Intelligence
AI Act	Artificial Intelligence Act
ALL	Acute Lymphoblastic Leukemia
ATMP(s)	Advanced Therapy Medicinal Product(s)
CAR-T	Chimeric Antigen Receptor T-cell therapy
CCRM Nordic	Centre for Commercialization of Regenerative Medicine
CDMO	Contract Development and Manufacturing Organization
DKFZ	Deutsches Krebsforschungszentrum / German Cancer Research Center
ECPDC	European Cancer Patient Digital Centre
EHDS	European Health Data Space
EISMEA	European Innovation Council and SMEs Executive Agency
ERN	European Reference Network
FINDATA	Finnish Health and Social Data Permit Authority
FHIN	Federated Health Innovation Network
GDI	Genomic Data Infrastructure project
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
GMS	Genomic Medicine Sweden
HL7 FHIR	Health Level Seven Fast Healthcare Interoperability Resources
HNPM	Hellenic Network of Precision Medicine
HTA	Health Technology Assessment
IMI	Innovative Medicines Initiative
IPR	Intellectual Property Rights
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico
IT	Information Technology
IVDR	In Vitro Diagnostic Regulation
JCA	Joint Clinical Assessment
MDR	Medical Device Regulation
NGP	National Genomics Platform
OMOP CDM	Observational Medical Outcomes Partnership Common Data Model
PADRIIS	Data Analytics Program for Health Research and Innovation
PM	Personalised Medicine
PRECISEU	PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUROpe

ROGEN	Romanian Genomic Data Infrastructure project
RSA	Risk-Sharing Agreement(s)
RSNN	Regulatory Science Network Netherlands
SME(s)	Small and Medium-sized Enterprise(s)
SNOMED CT	Systematized Nomenclature of Medicine
ZPM	Zentrum für Personalisierte Medizin / Center for Precision Medicine



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EXECUTIVE SUMMARY

The PRECISEU project—PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope—aims to accelerate the development and equitable implementation of personalised medicine (PM) across Europe. This D6.1 Cross-Regional Report, led by Sahlgrenska Science Park, maps systemic barriers and promising practices in ten European regions/countries: Flanders (BE), Sofia (BG), Catalonia (ES), Baden-Württemberg (DE), Crete (EL), Emilia-Romagna (IT), Lithuania, the Netherlands, North East Romania, and Västra Götaland (SE).

Personalised medicine, driven by health data, genomic insights, and advanced technologies such as ATMPs, holds major promise for delivering the right treatment to the right patient at the right time. By combining these capabilities, it enables better outcomes, greater efficiency, and continuous innovation in healthcare. However, its adoption faces interlinked challenges:

- Health data access and governance: Fragmented, siloed systems; inconsistent standards; legal uncertainty under GDPR; and complex, inconsistent consent processes hinder secure sharing and reuse of data.
- Financial barriers: Outdated reimbursement models, high development costs, limited investment—especially for SMEs—restrict market access and scalability.
- Regulatory hurdles: Unclear or fragmented pathways for AI tools, Advanced Therapy Medicinal Products (ATMPs), and hospital exemptions delay adoption and raise costs.
- Competence and awareness gaps: Shortages of specialised skills across healthcare and industry; low patient awareness and engagement; and limited policymaker understanding slow integration into practice.
- Healthcare readiness: Infrastructure deficits, regional inequities, and concentration of services in academic centres limit equitable access.
- Innovation ecosystem constraints: Weak cross-sector coordination, lack of shared manufacturing/testbed facilities, and barriers to clinical trial participation reduce the translation of innovation into patient benefit.

The report also compiles good practices—from national genomic platforms and federated data networks to risk-sharing payment models, regulatory science initiatives, and targeted training programmes—that show how targeted investment and collaboration can address these barriers.

By mapping key barriers and emerging solutions, this report creates a critical foundation for understanding where support is most needed to strengthen innovation and accelerate the adoption of personalised medicine. Drawing on these insights, the project will establish a joint roadmap and open innovation model to drive adoption through aligned policies, targeted



support, and scalable solutions. This coordinated effort aims to ensure that personalised medicine innovations reach patients faster, more equitably, and with greater impact across Europe.



ABOUT THIS REPORT

Personalised medicine (PM) is reshaping the future of healthcare by enabling more precise, preventive, and patient-tailored care. Defined by the European Council as a model that uses individual biological characteristics to deliver “the right therapeutic strategy for the right person at the right time,” it offers transformative potential for patients, healthcare systems, and innovation ecosystems alike. Personalised medicine is important not only for improving health outcomes but also for making healthcare more efficient. By targeting treatments to those most likely to benefit, PM can reduce trial-and-error prescribing, avoid unnecessary interventions, and support earlier diagnosis and prevention. It is especially vital in areas such as oncology, rare diseases, and pharmacogenomics, where traditional treatment approaches often fall short.

Personalised medicine is transforming healthcare by delivering more precise, timely, and effective treatments—improving patient outcomes while optimizing resources and reducing unnecessary interventions.

The development and implementation of precision-based approaches face unique and complex challenges that differ from conventional healthcare innovation. Precision methods and treatments are often designed for small, biomarker-defined patient subgroups, requiring advanced diagnostics, real-time data integration, and the co-development of companion diagnostics. Manufacturing processes - particularly for cell and gene therapies and other Advanced Therapy Medicinal Products (ATMPs) - are typically less scalable and significantly more costly.

Effective implementation also relies on access to and analysis of large, diverse datasets, including genomic, clinical, and lifestyle information. This demands interoperable digital infrastructure and robust health data governance, areas where many health systems remain insufficiently prepared. Furthermore, existing reimbursement frameworks struggle to capture the long-term value of these targeted interventions, and regulatory systems have not fully adapted to their complexity and specificity. Combined with high development costs, limited translational infrastructure, and a fragmented policy environment, these factors create major bottlenecks in bringing personalised innovations to market and integrating them into everyday clinical practice.

Tailored care requires advanced tools and complex production, making precision medicine far more demanding than traditional healthcare.

Personalised medicine not only represents a transformative force for clinical care but also serves as a strategic economic opportunity for Europe. Advancing deep-tech innovation in healthcare is central to Europe’s vision for global leadership, economic growth, and societal



well-being. As healthcare becomes increasingly data-driven and focused on precision therapies, Europe's competitiveness and long-term resilience will depend on its capacity to foster and scale breakthrough solutions in this rapidly evolving field.

As emphasized by EU institutions and the 2024 Draghi report on European competitiveness, personalised medicine is not only a public health imperative—it is a pillar of Europe's technological leadership and economic sovereignty.

To fully realise the potential of personalised medicine in Europe, it is vital to address a series of interconnected challenges through a coordinated, multi-level approach. Achieving this requires a clear understanding of the diverse barriers and enablers that influence regional capacities and readiness. This report responds to that need by mapping key obstacles and identifying promising practices across European regions.

This work has been carried out within the framework of the PRECISEU project, which aims to accelerate the development and equitable implementation of personalised medicine by identifying systemic barriers, engaging regional stakeholders, and promoting solutions that are both scalable and transferable. PRECISEU leverages cross-regional insights and collaboration to guide evidence-based strategies that foster innovation, enhance health system integration, and expand patient access to personalised care across Europe.

The report summarises the main barriers affecting the development, market entry, and implementation of personalised medicine across Europe. Drawing on regional findings, it highlights challenges related to health data access, financing, regulation, skills, healthcare readiness, and innovation ecosystems—while also showcasing promising local and international initiatives. It offers a cross-regional market mapping designed to identify the main barriers that must be addressed to improve access and implementation results.

In addition to this cross-regional analysis, the report includes individual regional and country-level fact sheets. These provide overviews of the current state of personalised medicine in each participating region or country, outlining local strengths and challenges. Together, these fact sheets enrich the broader analysis by providing region-specific insights that can guide targeted action at both national and EU levels.

Methodology

Aim

The aim was to identify the most significant challenges hindering personalised medicine innovations from reaching patients and markets across Europe, and to capture good practices and strategies that can help overcome these barriers. By collecting insights from ten different regions, the aim was to provide a common view of the main barriers to the development and implementation of precision care, while supporting the future creation of a joint European roadmap for faster and more effective adoption.

Regions involved

The work was carried out across ten European regions, each represented by local partners with strong ties to their respective healthcare and innovation ecosystems. These regions/countries included Flanders in Belgium, Sofia in Bulgaria, Catalonia in Spain, Baden-Württemberg in Germany, Crete in Greece, Emilia-Romagna in Italy, Lithuania, the Netherlands, the North-East Region of Romania, and Västra Götaland in Sweden.



Map of the ten participating European regions/countries

Overall approach



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A shared methodology was developed and followed by all regions to ensure consistency, while still allowing some flexibility based on local contexts. The process started with stakeholder interviews to gather insights from people working in academia, healthcare, industry, and other parts of the ecosystem. These findings were then used to draft regional reports. The reports served as the basis for workshops where stakeholders could meet to discuss, validate, and deepen the findings. After the workshops, each region updated their report to include the new insights. Finally, the results from all regions were brought together and analysed to identify common patterns of challenges across Europe.

Country	Region	Total	Industry & Private Sector (incl SME)	Healthcare Providers	Research & Academia	Public Authority or other
Belgium	Flanders	14	7	2	1	4
Bulgaria	Sofia	44	18	3	9	14
Spain	Catalonia	15	6		4	5
Germany	Baden-Württemberg	10	2	2	6	
Greece	Crete	10	4		3	4
Italy	Emilia-Romagna	14	4	1	3	6
Lithuania	Lithuania	11	3	1	3	4
Netherlands	Netherlands	12	2	1	4	5
Romania	North-East Region	10	1	1	6	2
Sweden	Västra Götaland	18	5	3	3	7
Total		158	52	14	42	51

Tab 3. Number of expert interviews conducted by country representatives in each country/region.

Interviews with stakeholders

The first phase involved in-depth interviews, guided by a shared interview protocol. These conversations focused on identifying the main access barriers to personalised medicine, examples of successful practices, and challenges around accessing secondary health data. Each region aimed to conduct around ten interviews with representatives from key groups like academia, healthcare providers, SMEs and larger companies, public authorities, ecosystem representatives, and patient organisations. The interviews took place during January and February 2025 and were mostly held online, lasting 30 to 60 minutes. A common invitation letter and question guide ensured that interviews across regions covered the same core topics. Notes and quotes from the interviews were collected and analysed to identify recurring themes and region-specific insights.

Drafting the regional reports

After the interviews, each region compiled a draft regional report using a common template¹. The reports included sections on the most important barriers, strengths and weaknesses of the regional ecosystem, examples of best practices, and access to health data. These drafts were

¹ See Appendix 2 – Regional Report Template

shared with local stakeholders before the workshops so they could review and comment on the findings in advance.

Workshops for validation and dialogue

During March 2025, each region² hosted a workshop—either in person or online—with participants from the interviews and other relevant actors. The workshops were designed to confirm the key barriers, gather different perspectives, and discuss the region’s strengths and weaknesses in personalised medicine. Using group discussions participants helped refine the findings and bring in new viewpoints. Most workshops involved 10 to 40 participants, representing a mix of sectors and roles. Notes and outcomes from the workshops were documented and used to update the regional reports.

Country	Region	Workshop participants	Online/ on site	Workshop organizer(s)
Belgium	Flanders	13	Online	MEDVIA
Bulgaria	Sofia	44	On site	Health and Life Sciences Cluster (HLSC) and SIA
Spain	Catalonia	35	Online	ACCIO, Departament de Salut, support by BIOCAT
Greece	Crete	29	Online	FORTH-ICS
Italy	Emilia-Romagna	11	On site	Clust-ER Health and ART-ER
Lithuania	Lithuania	14	On site	Innovation Agency Lithuania
The Netherlands	The Netherlands	7	Online	EATRIS
Romania	North-East Region	23	On site	IMAGO-MOL Cluster
Sweden	Region Västra Götaland	23	On site	Sahlgrenska Science Park, Sahlgrenska University Hospital
Total		199		

Tab 4. Market and Patient Access workshops held in respective region.

² All regions/countries held a workshop, except Germany, where one-on-one expert consultations were used instead.

Finalising the regional reports

Once the workshops were completed, the regional teams revised their draft reports and prepared final versions in English. These reports brought together the validated barriers, updated examples of good practices, and a summary description of the regional healthcare and innovation system. The final reports served both as standalone insights for each region and as input into the cross-regional analysis.

Cross-regional analysis

All regional results were compared and synthesised into this cross-regional report. This final step focused on identifying recurring barriers that, while often rooted in local contexts, are strikingly similar across regions. Notably, regions with a more mature ATMP ecosystem tended to focus their discussions on challenges and opportunities related to advanced therapies, while regions with less developed ATMP structures placed stronger emphasis on health data and its role in enabling personalised medicine. By highlighting these shared challenges alongside region-specific emphases, the report underscores systemic issues and EU-level policy gaps that hinder the implementation of personalised medicine. It also showcases good practices with potential for adaptation across countries.

Through this coordinated but locally rooted approach, a wide range of experiences and viewpoints from across Europe have been captured. The insights collected will help guide future efforts to improve access to personalised medicine and create more connected, supportive innovation ecosystems at both regional and EU levels.



OVERVIEW OF MAIN BARRIERS

This section presents a comprehensive overview of the 17 main barriers hindering the development, market entry, and clinical adoption of personalised medicine, based on insights gathered from ten European regions.

The barriers are organized into six overarching categories that reflect their systemic nature. For each barrier, a short description is provided, accompanied by illustrative regional quotes and, where applicable, examples of good practices that address the issues.

Health accessibility	data	1. Health data fragmentation
		2. Health data governance
		3. Legal interpretation regarding health data use
		4. Consent management of health data
Financial barriers		5. Reimbursement Misalignment
		6. High development costs and limited investment
Regulatory barriers		7. Regulatory uncertainty of AI in healthcare
		8. Regulatory complexity within the field of ATMPs
		9. Unclear rules for hospital exemption
Competence awareness	and	10. Competence gaps across healthcare and innovation ecosystems
		11. Patient awareness
		12. Understanding, knowledge and support from policy makers and decision makers
Healthcare readiness		13. Infrastructure-related barriers in healthcare
		14. Regional Inequities and centralization of services
Innovation ecosystem capacity		15. Barriers to scalability in ATMP innovation and manufacturing
		16. Innovation ecosystem and coordination challenges across all fields of precision medicine
		17. Access and integration of clinical trials and testbeds

HEALTH DATA ACCESSIBILITY

1. Health data fragmentation

Precision medicine relies fundamentally on timely access, integration, and analysis of high-quality data from multiple sources, including e.g. clinical records, genomics, imaging, and real-world evidence. Fragmented health information environments and outdated digital infrastructure undermine this core requirement, thereby limiting both clinical effectiveness and the scalability of innovation.

Fragmented systems and limited interoperability

A main barrier to personalised medicine is the fragmentation of health data across siloed systems, hospitals, laboratories, research centers, and administrative bodies—that lack interoperability and operate in isolation. This disconnection prevents the creation of comprehensive, longitudinal patient profiles essential for personalised diagnosis, treatment, and follow-up. The challenge is further compounded by the absence of standardized data models; inconsistent structuring, coding, and categorization of health information across institutions hinder the integration of clinical, genomic, and administrative data. Even where digital systems exist, many electronic health records and data platforms are not built to common exchange standards, making cross-system communication difficult or impossible. Data sharing often relies on manual processes that are time-consuming, error-prone, and resource-intensive—ultimately limiting real-time clinical decision-making and delaying access to personalised therapies.

Outdated Digital Infrastructure

Outdated health IT infrastructure remains a major barrier to precision medicine. Legacy systems lack the scalability, governance, and flexibility required for high-volume data and are poorly suited to AI integration, predictive analytics, or federated learning. As a result, the digital backbone of many healthcare systems is misaligned with the demands of modern precision medicine.

Quotes:

“Health data in Greece is collected and stored across numerous incompatible systems, using varied formats, coding languages, and standards. Hospitals, labs, insurance systems, and research registries often operate in silos without common data models, making it difficult to aggregate, compare, or reuse data efficiently. The absence of nationally enforced standards such as HL7 FHIR, SNOMED CT, or OMOP CDM limits interoperability and hinders both clinical decision support and research efforts.”- Greece



*"Fragmented and outdated hospital IT systems: Many hospitals operate on disconnected, outdated IT systems, preventing effective data sharing and interoperability." - **Bulgaria***

*"Differences in the semantic and syntactic standards of data sources make integration difficult." - **Germany***

*"AI tools and genomic analysis platforms cannot integrate easily into existing hospital workflows, causing resistance to adoption." - **The Netherlands***

*"The current structure with 21 regions causes fragmentation, with difficulties in accessing and sharing data across healthcare providers and research units. There is a strong need to implement national standards and infrastructure, including a national e-consent system, to enable secondary use of health data and sharing across regions." - **Sweden***

Comment:

The European Health Data Space (EHDS)³ provides a systemic EU-wide framework to unlock the potential of health data while addressing longstanding issues around legal clarity, governance, and data fragmentation. Its success will depend on effective implementation by Member States and alignment with existing data protection regimes like the GDPR.

Good Practice	Country	Description
National Genomic Platform (NGP) ⁴	Sweden	A national informatics infrastructure, NGP, set up to be available for both diagnostics within healthcare and for research. A future opportunity to combine information with Sweden's extensive national disease registers for research, potentially leading to new discoveries and breakthroughs in precision medicine.
Federated Health Innovation Network (FHIN) ⁵	Belgium	Federated Health Innovation Network (FHIN) is a network of nine healthcare institutions in Belgium which are committed to collaborating in data sharing and optimization of care.
CeGaT in Tübingen (Cancer Center Clinic Stuttgart) ⁶	Germany	CeGaT in Tübingen provides excellent service by directly contacting patients, offering quick feedback, and ensuring efficient sequencing processes. They handle sequencing projects from university hospitals and other institutions, emphasizing a patient-centered approach.

³ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

⁴ <https://genomicmedicine.se/en/data-management-informatics/>

⁵ <https://www.fhin.be/>

⁶ <https://cegat.com>

2. Health data governance

Coordinated health data governance is essential for unlocking the full potential of personalised medicine. As highlighted in the regional reports, fragmented policies, inconsistent standards, and heavy burdens on data custodians hinder the secure sharing and reuse of health data. Without clear frameworks and incentives, valuable datasets remain siloed, slowing research, innovation, and the development of tailored healthcare solutions.

Fragmented governance and infrastructure

There is a widespread lack of coherent national governance frameworks to oversee health data sharing. Institutional policies are often inconsistent, resulting in a fragmented and inefficient landscape. The absence of standardized procedures and oversight mechanisms leads to duplication of effort, administrative complexity, and low interoperability across data systems.

Burden on data custodians

Hospitals and research institutions, which serve as primary data custodians, frequently face high administrative, legal, and technical burdens when facilitating data access. Without tangible benefits or incentives, these stakeholders are often reluctant to engage in data-sharing initiatives. This limits the availability and reusability of valuable datasets for research and innovation.

Quotes:

"Although numerous data and good access to information exist, the networking of databases is not used consistently. There are many experts working intensively on the topic, but the 'swarm intelligence' in the field of precision medicine has not yet been sufficiently utilized. A lot of work runs in parallel, and everyone works in their own isolated system, which also applies to the ZPM (Center for Precision Medicine Ulm), which operates as an isolated system." - Germany

"There is no designated authority in Romania to which researchers can submit requests for secondary data use in medical research. This represents a significant barrier to evidence-based innovation in healthcare." - Romania

"The chosen multi-site solution in Germany has created unnecessarily complex structures that make data analysis difficult. Data must be sent back and forth between different data centers, clinics and research institutes instead of being stored at a central location as in other countries." - Germany

“Bulgaria also faces significant technical and financial challenges in secondary data access... hospitals have little financial incentive to share anonymized data for research purposes... AI-driven health innovations and large-scale epidemiological studies are hindered.” -Bulgaria

“The lack of national coordination and harmonisation in data sharing and access regulations across regions creates significant barriers to data interoperability and secondary use for research and clinical innovation.” - Italy

Good Practice	Country	Description
PADRIIS program ⁷	Catalonia, Spain	On 2017 Catalonia implemented the Data Analytics Program for Health Research and Innovation (PADRIIS6). It has the mission of making health data related to promoting research, innovation and health evaluation available to the scientific community through access to the reuse and cross-referencing of health data generated by the comprehensive public health system of Catalonia (SISCAT), in accordance with the legal and regulatory framework, the ethical principles and transparency towards the citizens of the program. Recently (i.e. March 2025), AQUAS has announced the tender for the creation of the Office for Access to Secondary Use Data in Catalonia (ODAS2). This action is part of the European and Council Regulation on the European Health Data Space (EHDS).
Hellenic Network of Precision Medicine (HNPM) ⁸	Greece	"HNPM" directly addresses several core challenges under Data Governance and Infrastructure, such as: Fragmented data systems, lack of integration between genomic and clinical data, absence of a unified infrastructure, data accessibility for researchers and clinicians
FINDATA ⁹	Finland	Findata provides a single point of access for secondary use of health and social care data, streamlining the process for researchers, innovators, and public institutions.
HealthRI ¹⁰	The Netherlands	Organization in the Netherlands dedicated to improving the reuse of health data for policy, research, and innovation to achieve a learning healthcare system. Mission is: Better health for citizens and patients by reusing health & life sciences data with an integrated data infrastructure to enable data driven research, innovation and policy.
Genomic Data Infrastructure (ROGEN) project ¹¹ +GDI project ¹²	Romania	The Genomic Data Infrastructure (GDI) project enables access to genomic and related phenotypic and clinical data across Europe. The Romanian Digitalization Authority participates in this complex project together with the Genomics Research and Development Institute. ROGEN project is currently creating Romania's National Reference Genome .

⁷ [https://aquas.gencat.cat/ca/fem/intelligencia-analitica/padris/index.html#googtrans\(ca|en\)](https://aquas.gencat.cat/ca/fem/intelligencia-analitica/padris/index.html#googtrans(ca|en))

⁸ <https://gsri.gov.gr/en/protovoulies-driseis/hellenic-network-of-precision-medicine-personalized-medicine/>

⁹ <https://findata.fi/en/>

¹⁰ <https://www.health-ri.nl/en/>

¹¹ University of Bucharest, partner in the project "Development of genomic research in Romania - ROGEN" - UniBuc - University of Bucharest

¹² European Genomic Data Infrastructure (GDI) project

Good Practice	Country	Description
Project on Secondary Use of Data ¹³	Lithuania	A first of a kind pilot project, centered on the secondary use of health data for startups. The aim is for this pilot project to evolve into a long-term initiative, helping startups integrate health data into their solutions more effectively, creating greater societal and socio-economic value.

3. Legal Interpretation regarding health data use

GDPR, while designed to protect individuals' data, is interpreted differently across EU Member States and even among institutions within the same country. This inconsistency has led to substantial barriers in the adoption of precision medicine and AI-driven healthcare solutions.

Inconsistent application and interpretation of GDPR

One major challenge is the fragmented understanding of what constitutes proper anonymization and consent. Health institutions, research organizations, and regulatory bodies often apply differing standards and procedures, which leads to uncertainty and risk aversion. As a result, access to secondary health data is frequently delayed or denied, even when such data could be used securely and ethically for research and innovation.

These disparities hinder the development and validation of artificial intelligence tools, obstruct collaborative research efforts, and limit the effective integration of real-world evidence into clinical practice. Stakeholders - including healthcare providers, academic researchers, and private sector innovators - struggle to navigate an unpredictable regulatory environment, leading to hesitation, inefficiencies, and missed opportunities for improving patient outcomes.

Quotes:

*"Compliance with GDPR and AI Data Act regulations creates barriers to accessing and utilizing secondary health data for AI-driven insights." - **Bulgaria***

*"Ambiguities in interpreting GDPR, limited national guidance on ethical approvals, and fragmented responsibilities across competent authorities create significant delays and uncertainty." - **Crete***

*"Access to secondary health data is severely restricted, mainly due to restrictive ethical guidelines and strict data processing requirements." - **Germany***

*"GDPR complicates the sharing of non-anonymized health data... Inconsistent interpretation of regulations across regions and EU member states (hospital exemption, GDPR)." - **Belgium***

*"There is no unified interpretation of GDPR in Sweden—opinions differ from one legal expert to another." - **Sweden***

¹³<https://inovacijagentura.lt/news/2024/09/lithuanian-health-data-pilot-for-startups-aims-to-enhance-cancer-treatment-effectiveness.html?lang=en>

"Regulation for secondary use of health data is also open to interpretation, creating discrepancies. Still ethical and legal constraints refrain some institutions from sharing data; being approvals by ethical committees one of the hurdles reported by few smaller companies." -**Spain**

"Accessing and using secondary health data is hindered by varying national data privacy laws and the cautious interpretation of GDPR, creating uncertainty for companies and researchers."

-Bulgaria

4. Consent management of health data

Inconsistent and underdeveloped approaches to managing consent have led to fragmented processes that create inefficiencies and legal uncertainty, ultimately discouraging data sharing across institutions and national borders.

Lack of harmonized consent mechanisms

Consent management for the secondary use of health data remains a complex and fragmented issue across regions. Frameworks for obtaining and managing patient consent are often unclear or inconsistently applied, particularly when data is shared beyond the institution where it was originally collected. In many cases, explicit consent is required for any secondary use, but this consent is typically valid only within the originating institution, creating additional hurdles for cross-institutional or cross-border data sharing. The lack of standardized procedures leads to delays and uncertainty, particularly when multiple approvals are needed. Interpretations of GDPR vary, and decentralized ethical oversight adds further complexity, resulting in inconsistencies and bottlenecks in consent handling making consent management a significant barrier to advancing personalised medicine and data-driven healthcare innovation.

Quotes:

"In clinical settings, patients provide informed consent for their medical data to be used for research purposes. However, under GDPR and current Romanian regulations, this consent is restricted to the institution where the data was collected—typically the hospital or university hospital. Importantly, tertiary use of data—that is, sharing with third parties beyond the original institution—is not currently covered by standard consent procedures in Romania." -**Romania**

"There are currently no good examples of a broader use of health data, as the collection and consent of patients is often problematic. For this reason, 'broad consent' has been developed, which should generally allow health data to be used for scientific evaluations." -**Germany**

"Complex opt-in processes, tedious consent workflows with limited digital options, no dynamic consent mechanisms and patients cannot easily update or withdraw their consent preferences."

Greece



FINANCIAL BARRIERS

5. Reimbursement Misalignment

Personalised medicine promises more targeted, effective healthcare, but its integration into health systems across Europe is being held back by outdated and incompatible reimbursement models.

According to the PRECISEU regional reports, traditional funding models are poorly suited to accommodate the high upfront costs of ATMPs or to capture the indirect and long-term benefits of advanced diagnostics and AI-driven digital health solutions. The lack of outcome-based pricing models, risk-sharing agreements, and tailored assessment pathways create systemic delays, financial uncertainty, and limited patient access.

Reimbursement mismatch limits access to personalised medicine

There is a fundamental mismatch between personalised medicine interventions, such as advanced diagnostics and advanced therapy medicinal products (ATMPs), and traditional reimbursement frameworks. These therapies often involve high upfront costs and generate long-term or indirect benefits, which existing funding models are poorly equipped to capture. As highlighted in the PRECISEU regional reports, this misalignment results in systemic difficulties in achieving reimbursement, particularly in the absence of robust real-world effectiveness data.

Many health systems still rely on short-term cost containment strategies and demand extensive comparative clinical and economic evidence, which is often unavailable at the time of market entry for precision therapies. As a result, reimbursement decisions tend to be conservative, with low coverage levels that fail to capture the full clinical value or broader health system impact of these innovations. The limited availability of robust health economic data further compounds this challenge, making it difficult to objectively demonstrate the long-term value of advanced diagnostics and therapies relative to their upfront costs. In practice, this misalignment means that healthcare providers are often left with little choice but to continue using standard treatments, even when more personalised—and potentially more effective—alternatives exist.

Rigid funding undermines value-based personalised medicine

The high upfront costs and long-term or uncertain benefits of personalised medicine make it difficult to accommodate within traditional and current reimbursement systems and payment models. The PRECISEU regional reports highlight the limited use and development of risk-sharing agreements and value-based pricing models, despite their potential to align payment with real-world outcomes. Without these mechanisms, healthcare systems face financial uncertainty, which slows the adoption of innovative therapies and limits patient access.

Reimbursement gaps delay AI health solutions

Across the PRECISEU regional reports, reimbursement of AI-driven digital health solutions and diagnostics is identified as a critical barrier to their integration into routine healthcare. These innovations often lack dedicated reimbursement codes and standardized pathways, which means that even clinically validated tools struggle to be adopted by hospitals or reimbursed by public payers. The lack of clarity in how AI tools are assessed for reimbursement, and the absence of tailored health technology assessment (HTA) processes, results in delayed or denied access for these solutions.

Quotes:

"Reimbursement challenges further limit patient access to potentially life-saving therapies. The fragmented reimbursement landscape also creates inequalities between patients from different regions." -Italy

"Current pricing and reimbursement models often fail to take into account the long-term social and economic benefits of these therapies." - Italy

"Current health economic models are outdated and do not reflect the therapeutic timelines associated with ATMPs." -Sweden

"Current reimbursement models do not align with the high upfront costs of precision medicine. This makes hospitals reluctant to adopt new therapies and discourages investment." - The Netherlands

"In Germany, only around two thirds of statutory health insurance funds have joined the selective contract to fund personalised oncology. As a result, one third of those insured have no access to these innovative therapies." -Germany

"High costs of manufacturing and treatment pathways coupled with reimbursement complexities leading to limited accessibility." -Belgium

"AI-driven diagnostics and digital health solutions often lack standardized reimbursement pathways, making it difficult for hospitals and clinics to integrate them into routine care." - Bulgaria

"New reimbursement models are needed to fund advanced therapies, gene therapies as well as new diagnostic technologies, which are more expensive than traditional ones." - Spain

"In Greece, the public healthcare system and private insurance providers face challenges with the reimbursement of these therapies, leading to out-of-pocket costs for patients and reluctance from providers to adopt them." -Greece



Good Practice	Country	Description
National Framework for Biomarker Reimbursement	Greece	This initiative addresses reimbursement gaps in precision medicine by establishing a national framework that links biomarker funding to health technology assessments, introduces budget tools for high-cost therapies, involves key stakeholders in pathway design, and seeks legislative support for ongoing policy updates.
Horizon Scanning Program	Italy	Several Italian regions have implemented Horizon Scanning programmes to anticipate the introduction of new advanced therapies. Regional task forces monitor upcoming therapies, estimate future costs and collaborate with pharmaceutical companies and institutions to gather data. The goal is to facilitate financial planning and ensure timely patient access.
Pay-for-performance model.	Germany	At the German Cancer Research Centre (DKFZ), the pay-for-performance model is used as a promising approach to improve access to innovative medicines.
mHealth ¹⁴	Belgium	Reimbursement of digital health solutions. Centralization and standardization of available information regarding available medical device software applications and their respective levels of reimbursement. Public tool available for general population, health care providers, etc.
National Procurement and Tendering	Denmark	Amgros does work for the regions that they would otherwise have to do themselves individually. Amgros has been using alternative agreement models for several years. These ensure that patients have access to new, expensive and innovative medicines.
Beneluxa Initiative	Belgium, The Netherlands, Luxembourg, Austria, Ireland	The Beneluxa initiative aims for sustainable access to, and appropriate use of, medicines in the participating countries. The initiative strive to increase patients' access to high quality and affordable treatments. The collaboration also allows the initiative to demand more transparency on the cost build-up of pharmaceutical products. Also crucial for the improvement of medicine pricing is increased transparency on pricing between countries.
Risk-sharing models (RSA) for innovative medicines ¹⁵¹⁶	Catalonia, Spain	RSAs are agreements between healthcare payers and pharmaceutical companies that link drug pricing to clinical or economic outcomes. Catalonia's decentralized healthcare system, managed by CatSalut, has implemented RSAs since 2011, formalizing a centralized approach in 2016. RSA are also applied in other regions in Spain.

¹⁴ [Belgian platform for medical mobile applications - mHealthBELGIUM](#)

¹⁵ Implementing Risk-Sharing Arrangements for Innovative Medicines: The Experience in Catalonia (Spain) Guarga, Laura et al. Value in Health, Volume 25, Issue 5, 803 – 809 <https://doi.org/10.1007/s40273-021-01046-1>

¹⁶ Reyes-Travé, A., Guarga-Solé, L., Roig-Izquierdo, M. et al. Characterization of the Pharmaceutical Risk-Sharing Arrangement Process in Catalonia. *PharmacoEconomics* **39**, 973–982 (2021). <https://doi.org/10.1007/s40273-021-01046-1>

Good Practice	Country	Description
Joint Clinical Assessment (JCA) of medicinal products (EU) ¹⁷	EU	The Joint Clinical Assessment (JCA) is a key component of the EU Health Technology Assessment (HTA) Regulation (EU 2021/2282), which aims to harmonize the evaluation of medicinal products and certain medical devices across EU member states. The aim of JCA is not to replace the national reimbursement process or pricing negotiations currently performed by the individual EU Member States but to add/improve existing procedures by creating a way for pan-European collaboration and information sharing across Europe.

6. High development costs and limited investment

The development of precision medicine—including advanced therapy medicinal products (ATMPs) and AI-driven diagnostics—entails significant financial demands. These costs arise from a combination of scientific, operational, and regulatory complexities that collectively hinder the scalability and sustainability of innovation in this sector.

High development costs

One of the most pressing cost drivers is the complex and individualized nature of many precision therapies. Treatments like CAR-T cells require bespoke manufacturing, advanced infrastructure, and rigorous quality control, all tailored to individual patients. Unlike conventional pharmaceuticals, these therapies do not benefit from economies of scale, resulting in substantially higher per-unit costs. Advanced therapies for rare diseases, especially stem cell-based treatments, may be discontinued by pharmaceutical companies due to low profitability, even if they are effective and approved.

Regulatory burdens also contribute to escalating costs. Early-phase clinical trials often face the same level of scrutiny as late-phase studies, increasing both time and financial investment required for market entry. For AI-based tools, every algorithm update may trigger a new validation and approval cycle, creating continuous and costly regulatory obligations.

Additionally, the limited access to high-quality data significantly constrains the development of AI-driven diagnostics. Due to strict compliance requirements and fragmented data systems, real-world validation becomes difficult and expensive, further delaying product readiness and increasing costs.

Funding and investment barriers

Small and medium-sized enterprises (SMEs) and start-ups are key drivers of innovation in precision medicine but face significant funding and investment obstacles that restrict their growth and impact.

A core issue is limited access to capital. The capital-intensive demands of personalised medicine—ranging from R&D to regulatory compliance—are particularly burdensome for

¹⁷https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

smaller entities. Compared to larger firms, start-ups have fewer avenues to secure sufficient public or private investment to advance their technologies.

There is also high financial risk and investor hesitancy. Long development cycles, uncertain market sizes (especially for rare diseases), and the absence of clear commercialisation pathways deter many investors. Venture capital, which often prioritises quick returns, is not well aligned with the realities of personalised medicine development.

A fragmented investment ecosystem and dependency on external support further limit progress. Public grants and subsidies are often misaligned with commercialisation needs, and the lack of bridging finance—such as follow-on funding or risk-sharing models—leads to the premature stagnation of promising innovations.

Quotes:

“Italy ranks 17th in the EU in venture capital (VC) investment as a percentage of GDP... most [VCs] are focused on early-stage investments, lacking the capacity to support later-stage growth.”-Italy

“In Sweden, there is limited capital and few specialist investors with expertise in the field... Small investors often expect a faster return on investment than the 7–10 years typically required.”-Sweden

“Companies face higher costs and unpredictable timelines for market entry, discouraging investment in new therapies and reducing the incentive to develop innovative treatments.”- Italy

“There is a lack of knowledge and awareness among investors and policymakers regarding the specific needs and economic potential of ATMPs and personalised medicine innovations.”-Belgium

“The complexity and long-term nature of precision care technologies make it challenging to attract investments.”- Lithuania

REGULATORY BARRIERS

7. Regulatory uncertainty of AI in healthcare

AI innovations are essential to the development of personalised medicine, enabling more accurate diagnostics, predictive analytics, and tailored treatment decisions based on complex patient data. As highlighted in the PRECISEU reports, most regions lack national standards for clinical AI tools and dedicated testing environments, such as regulatory sandboxes.

Lack of standardized frameworks for AI validation

There is a widespread absence of established regulatory pathways or nationally coordinated frameworks for validating AI tools used in clinical settings. This includes missing guidance on



clinical-grade AI performance standards, transparency requirements, and algorithm updates. The result is delayed adoption and integration of AI-driven decision support tools.

Absence of regulatory sandboxes and testing environments

Few countries or regions have implemented dedicated sandbox environments or pilot programs that allow controlled testing of AI technologies within healthcare. This lack of structured testing infrastructure prevents safe experimentation, evaluation, and iterative development, which are critical for building trust and regulatory readiness.

Quotes:

"Some suggest regulatory sandboxes—controlled environments where companies and institutions can test new technologies under guided compliance—could help navigate legal uncertainties." -The Netherlands

"AI and biomarker innovations often require compliance with MDR/IVDR, but the regulatory path is unclear and time-consuming." -The Netherlands

"There is currently no standardized framework for validating AI algorithms used in clinical decision support systems in Greece." -Greece

"Current regulations do not differentiate between minor AI model improvements and entirely new software, forcing companies to revalidate AI tools even for minor updates." - Bulgaria

"Emerging solutions such as Data Lakes, Federated Learning, and Sandboxes have been proposed to facilitate secure access while preserving data privacy. However, their implementation remains complex and inconsistent across different institutions and countries." -Italy

Comment:

The EU Artificial Intelligence Act (AI Act)¹⁸ mandates validation, transparency, quality management, and risk controls for high-risk AI systems, including those used in healthcare. It also encourages the establishment of regulatory sandboxes to support innovation and supervised testing but does not make them mandatory. As a result, their implementation depends on national initiatives, leading to variations and gaps across regions.

Good Practice	Country	Description
BeginNGS Greece ¹⁹	Greece	This initiative directly tackles complex regulatory and ethical issues around the use of genomic data, AI-based variant interpretation, and cross-sector collaboration, within a real-world pilot setting

¹⁸ <https://artificialintelligenceact.eu/ai-act-explorer/>

¹⁹ <https://www.firststeps-ngs.gr/>

8. Regulatory complexity within the field of ATMPs

Advanced Therapy Medicinal Products (ATMPs) are among the most complex medical products to regulate because they blur the lines between pharmaceuticals, medical devices, and human-derived substances.

Highly complex regulatory environment

Across regions, stakeholders consistently highlight that the regulatory environment for ATMPs is highly complex, fragmented, and administratively burdensome. These therapies are subject to multiple layers of oversight, including stringent safety, efficacy, quality assurance, and Good Manufacturing Practice (GMP) standards. The process involves navigating various approval stages—from preclinical studies and clinical trials to manufacturing validation and post-market monitoring.

Overlapping regulatory frameworks

The complexity is intensified by the interplay between overlapping regulatory frameworks, particularly when ATMPs are combined with companion diagnostics, infusion systems, or biomaterials. The divergence between regulations for pharmaceuticals, medical devices, and human-derived substances creates additional administrative burdens and legal uncertainty, particularly for innovators and small developers.

This fragmented regulatory landscape contributes to delays, increased costs, and limited accessibility of ATMPs, acting as a significant bottleneck to their clinical adoption. Although such rigorous regulations are recognized as essential for patient safety, the lack of streamlined and harmonized pathways is widely viewed as a structural barrier to advancing precision medicine in Europe.

Quotes:

"Many precision care innovations, including AI-driven diagnostics and gene therapies, face complex regulatory pathways that vary by country... very time-consuming... a significant hurdle for smaller companies." -The Netherlands

"A regulatory 'mindset' needs to be established very early in the process if the idea or research has the potential to reach patients—otherwise, the commercialization process will be lost. Small companies and researchers who miss this step are at risk". -Sweden

"The regulatory process is mainly described as complex, lengthy, unclear and costly... regulations are open to interpretation... increasing the cost of development." -Spain

"The lack of simplified, centralised regulatory processes adds complexity and makes Italy a less attractive destination for early clinical research." -Italy

“The regulatory landscape for precision care innovations is often unclear and inconsistent, creating significant obstacles for innovators. Uncertainty about the application of gene editing beyond plants, and the lack of clear guidelines at national and European levels, leads to confusion and delays. Innovators face challenges in understanding regulatory requirements and navigating complex approval processes, which vary between countries and regions.”-Lithuania

“Regulatory approval processes for precision medicine therapies... are often lengthy, fragmented, and complex... requiring compliance with various national and EU-level regulations... significantly delaying adoption and innovation.”-Bulgaria

Good Practice	Country	Description
Regulatory Science Network Netherlands (RSNN) ²⁰	The Netherlands	Regulatory Science Network Netherlands (RSNN) is a network of experts from industry, academia, government bodies, and the broader regulatory science field. Our mission is to advance an efficient and effective regulatory system that supports medicines development, marketing authorization, access, and appropriate use of medicines.
Regulatory Fast Track for Unmet Medical Needs ²¹	USA	The US FDA has a mechanism that can fast track therapies that fill an unmet medical need or offer a superior product to address medical needs.
FDA CATT Program ²²	USA	The FDA Centre for Advanced Therapies Technologies (CATT) program facilitates discussions between regulatory bodies and companies developing advanced manufacturing technologies. It provides interactive support, reducing regulatory uncertainties and accelerating technology adoption. The initiative has already influenced regional companies (Emilia-Romagna, Italy), guiding quality control development for the next three years.

9. Unclear rules for hospital exemption

The Hospital Exemption is a regulatory pathway allowing certain ATMPs to be prepared and used without centralized marketing authorization. It applies to custom-made products prepared on a non-routine basis for individual patients, used within the same Member State under the exclusive responsibility of a medical practitioner. Currently there is a lack of clear, harmonized guidelines across regions on how hospital exemptions for ATMPs should be implemented.

Inconsistent application

²⁰ <https://www.rsnn.nl/>

²¹ <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

²² <https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-team-catt>

Hospital exemptions are applied differently across jurisdictions, leading to fragmentation in access and limiting the scalability of hospital-based ATMP initiatives. This inconsistency complicates efforts to ensure quality, safety, and equitable patient access.

Discouragement of innovation

The regulatory complexity and lack of standardized processes discourage hospitals and research institutions from pursuing ATMP development under hospital exemption pathways, despite their potential to deliver life-saving treatments, especially for rare or unmet medical needs.

Competition and misalignment with commercial pathways

Concerns are raised about hospital exemptions potentially bypassing formal regulatory channels, which may create tensions between public healthcare institutions and private sector developers, and raise questions about long-term sustainability and oversight.

Quotes:

"ARI-0001 is the first CAR-T therapy fully developed in Europe. It targets CD19+ B-cell malignancies, specifically relapsed/refractory acute lymphoblastic leukemia (ALL) in patients over 25 years-old.. ..Early in 2021 the Spanish Agency of Medicines and Medical Devices (AEMPS) approved ARI-0001. The therapy was authorized via the hospital exemption (HE) under EU/Spain's ATMP regulations"-Spain

"Inconsistent interpretation of regulations across regions and EU member states (hospital exemption, GDPR). Ambiguity in hospital exemption usage for ATMPs potentially leads to underutilization..."-Belgium

"The hospital exemption – a potential barrier to commercialisation, but an enabler for patient access?... When products are developed within healthcare institutions, this may have significant consequences; it could potentially remove incentives for pharmaceutical development... SMEs struggle to compete with 'in-house' hospital products."-Germany

COMPETENCE AND AWARENESS

10. Competence gaps across healthcare and innovation ecosystems

The implementation of personalised medicine depends on specialised skills across healthcare and innovation systems. As reported in the PRECISEU regional assessments, widespread gaps in areas such as genomics, bioinformatics, and digital health are slowing adoption and limiting clinical integration. Small and medium-sized enterprises (SMEs) also face significant competence needs, particularly in regulatory knowledge, market access, and business development—further constraining the translation of innovation into practice.

Healthcare competence and training gaps

A significant barrier to the implementation of precision medicine is the shortage of professionals with the necessary specialized expertise. Precision medicine demands multidisciplinary knowledge in areas such as genomics, molecular diagnostics, bioinformatics, and data-driven clinical decision-making. However, many healthcare systems lack sufficient numbers of qualified physicians, pharmacists, nurses, and bioinformaticians capable of delivering or supporting precision care. This workforce gap limits the capacity of healthcare institutions to adopt and scale precision medicine services effectively.

Closely linked to the personnel shortage is the lack of accessible, specialized education and training programs. Existing medical and professional curricula often fail to adequately address the competencies required for precision medicine. As a result, frontline healthcare providers frequently lack familiarity with emerging tools, methodologies, and technologies central to personalized care. This educational deficit reduces confidence in clinical decision-making, impedes the integration of novel diagnostics and therapies, and slows the overall adoption of precision medicine across care settings.

Innovation ecosystem competence and awareness gaps

Across multiple regions, developers and small- to medium-sized enterprises (SMEs) face common competence barriers that impede the advancement of ATMPs and health data-driven innovations toward successful market adoption.

One key barrier is limited regulatory competence and strategic awareness among early-stage companies and researchers. Many lack the expertise needed to navigate complex regulatory requirements for ATMPs and health data compliance. Without early alignment with regulatory standards and a clear understanding of market authorization pathways, innovations often experience significant delays or fail to progress to commercialization.

Another major challenge lies in the gaps in business development and commercialization skills. While scientific and clinical expertise may be well-established, many actors lack the strategic and entrepreneurial capabilities required to advance innovations toward market readiness.

In addition, there is a notable lack of specialized training in ATMP manufacturing, health data management, and digital health technologies. Many SMEs struggle to access professionals with the skills needed to manage the regulatory, technical, and clinical complexities of precision medicine. This skills gap restricts their ability to grow, scale, and deliver high-impact innovations within increasingly competitive and regulated markets.

Quotes:

*"The absence of structured, multidisciplinary education programs for healthcare professionals limits the optimisation of diagnostic and therapeutic applications, slowing the overall implementation of precision medicine." - **Italy***

*"A gap exists in skills related to ATMP development, particularly in terms of commercialising research." - **Sweden***

*"There is a lack of necessary competencies and education among healthcare professionals and decision-makers... Many healthcare providers lack the training needed to implement precision care technologies effectively." - **Lithuania***

*"There is a limited number of trainings on the development, technology transfer, production and commercialisation phases of precision medicine innovations, leading to a limited number of industry professionals with the sets of skills required for the successful growth of precision medicine companies." - **Italy***

*"Many clinicians lack training in molecular diagnostics, AI-driven decision support, and personalized treatment approaches, which slows down adoption." - **The Netherlands***

*"There is a need for hiring specialized personnel in data analysis to ensure the accurate interpretation and use of collected data." - **Romania***

*"Lack of healthcare professionals with specialized training in areas relevant to the implementation of PM, such as geneticists or bioinformaticians." - **Spain***

*"Healthcare institutions lack the resources to provide adequate training and professional development to staff on new digital health tools and precision medicine approaches." - **Greece***

Good Practice	Country	Description
Regulatory Science Network Netherlands ²³	The Netherlands	Regulatory Science Network Netherlands (RSNN) is a network of experts from industry, academia, government bodies, and the broader regulatory science field. With a mission to advance an efficient and effective regulatory system that supports medicines development, marketing authorization, access, and appropriate use of medicines.
Advance course on cell and gene therapies 2025 ²⁴	Italy	The Italian Health Institute (Istituto Superiore di Sanità) and EATRIS organised a 5-day training course open to 30 European participants from industry and academia, focused on all the aspects related to ATMPs, from pre-clinical development phase to clinical and regulatory requirements, manufacturing and quality control.
MSc in Precision Medicine and Novel Therapies ²⁵	Crete, Greece	This postgraduate program is explicitly designed to upskill healthcare professionals and biomedical scientists in genomics, bioinformatics, and personalized medicine—directly tackling the systemic lack of digital and data-driven literacy that hinders implementation of precision health in Greece.
Spinoff Initiative: 360 Degrees Labs ²⁶	Bulgaria	Training programs for healthcare professionals on how to interpret AI-generated insights and integrate them into clinical decision-making.
ATMP skill development projects ²⁷	Västra Götaland, Sweden	A new cross-sectoral initiative for ATMP workforce development has been launched, built on a joint work plan comprising two complementary projects: one focused on upskilling SMEs and the other on training healthcare professionals.

11. Patient awareness

Effective implementation of precision medicine builds on active patient engagement and the efficient sharing of health data.

Lack of patient knowledge and awareness

A lack of patient awareness is a recurring barrier to the adoption and implementation of personalised medicine. In many regions, patients are not fully informed about what personalised medicine entails, how it differs from traditional care models, or the specific advantages it may offer compared to usual clinical practice. This knowledge gap contributes to limited demand for genomic testing and reluctance to engage with innovative therapies.

Furthermore, in many regions, concerns were raised about patients' limited understanding of how their health data—especially genetic and clinical information—contributes to the development and delivery of personalised care. Patients are often unfamiliar with the role of data sharing in advancing medical research, supporting algorithm development, and optimising treatment outcomes. In particular, the use and benefits of AI-supported diagnostics and data-driven treatment planning are not widely recognised.

²³ <https://www.rsnn.nl>

²⁴ <https://eatris.eu/events/advance-course-on-cell-and-gene-therapies-2025/>

²⁵ <https://www.eap.gr/en/preth/thematikes-enotites/>

²⁶ <https://360lab.biocluster.bg/>

²⁷ <https://www.sahlgrenska.se/project-partnership/atmp-workforce-development-initiative>



This gap in understanding is further reinforced by concerns about data privacy, unclear communication regarding how health data is handled, and insufficient guidance from healthcare professionals. Even in settings where secure infrastructure and ethical safeguards exist, such uncertainty may lead patients to hesitate or refuse to share their data. Several regions specifically highlighted that patients are not always fully informed about their rights and choices concerning data consent. Opt-in and opt-out mechanisms were described as overly complex or inconsistently communicated, contributing to ongoing confusion and mistrust.

Quotes:

"The public is not sufficiently informed about the benefits and possibilities of personalised medicine. Most people do not know what PM is, how it works, and what benefits it can provide to patients."

-Lithuania

"Lack of patient education on precision medicine makes it difficult for individuals to understand and demand personalized treatments. Concerns about data privacy and genetic testing create resistance to participating in clinical trials and AI-based diagnostics."

-The Netherlands

"A significant number of patients lack awareness regarding the possibilities presented by precision medicine and ATMPs... Patients are frequently passive participants in the decision-making processes... This lack of engagement can lead to suboptimal outcomes."

-Italy

"General lack or insufficient awareness among citizens and healthcare providers regarding available personalized healthcare options."

-Belgium

"Patients often do not know if they are receiving the necessary diagnostics to determine if they are eligible for personalized treatments... They may be excluded from personalized treatment approaches if they are not informed about their options."

-Germany

"Complex opt-in processes: Tedious consent workflows with limited digital options. Low awareness among patients: Lack of awareness on the benefits of sharing health data for research."

-Greece

Good Practice	Country	Description
Patient-oriented events and the integration of personalized medicine in the Centre for Precision Medicine ZPM ²⁸	Baden-Württemberg, Germany	The Center for Personalized Medicine (ZPM) in Ulm organizes patient-oriented events in collaboration with self-help groups and patient organizations. These events allow patients to engage directly with experts, empowering them to better understand their condition and explore treatment options. The goal is to provide patients with a platform to actively participate in their treatment decisions.

²⁸ <https://www.uniklinik-ulm.de/en/zpmu.html>

Good Practice	Country	Description
An operational concept for a European Cancer Patient Digital Centre ²⁹	EU	This study presents a blueprint for implementing the European Cancer Patient Digital Centre (ECPDC). One of the focus areas being improving health data sharing. It outlines a framework for enabling citizens and patients to access and share their cancer-related data in a standardized, interoperable manner across all EU Member States. The initiative aims to enhance patient engagement in treatment decisions and research participation through a unified digital portal.

12. Understanding, knowledge and support from policy makers and decision makers

A recurring theme across regional reports is the limited understanding and strategic engagement of policymakers and decision-makers with the evolving field of precision medicine. In several regions, decision-makers lack sufficient awareness of the clinical, economic, and societal value of personalised medicine, which contributes to delays in regulatory approvals, rigid reimbursement frameworks, and fragmented policy support.

Budget Adaptation Needed

Policymakers often underestimate the long-term cost-effectiveness of precision approaches, instead prioritizing short-term budget constraints that hinder investment in essential infrastructure and innovation. This limited perspective slows the integration of technologies such as AI-driven diagnostics, genomic testing, and advanced therapy medicinal products (ATMPs) into healthcare systems.

Lack of Policy Coordination

Moreover, the absence of cohesive policy frameworks and coordination mechanisms at both national and regional levels results in fragmented implementation. Where regional disparities in access are overlooked, or where local providers are excluded from national strategies, systemic inefficiencies persist.

Quotes:

"Although Romania has one of the most advanced legislative frameworks in this area, we have increasingly fallen behind compared to other countries that have already implemented genomic medicine, precision oncology, or personalized prevention strategies."-Romania

"Limited knowledge among policymakers about the benefits and cost-effectiveness of precision medicine leads to slow regulatory approvals and rigid reimbursement policies."-The Netherlands

"Lack of specific and detailed knowledge on innovative reimbursement models for ATMPs has been suggested as one of the current barriers impacting the deployment of PM in Catalonia."-Spain

²⁹<https://op.europa.eu/en/publication-detail/-/publication/495c3a52-2161-11ef-a251-01aa75ed71a1/language-en>

"Lack of unified strategic direction at federal and regional levels for PM at large."-Belgium

"Failure to recognize the long-term cost benefits of precision medicine results in short-term cost-cutting measures that hinder innovation."-The Netherlands

HEALTHCARE READINESS

13. Infrastructure-related barriers in healthcare

The effective implementation of precision medicine is critically dependent on the availability of modern, integrated infrastructure. However, the analysis across regions reveals a series of persistent infrastructural deficits that significantly hinder the transition of precision medicine from research settings into routine clinical care.

Diagnostic infrastructure

A key barrier is the insufficiency of diagnostic infrastructure, including a lack of advanced laboratories, high-throughput sequencing platforms, and bioinformatics pipelines. These limitations constrain the routine application of genomic and biomarker-based diagnostics, which are fundamental to delivering targeted therapies. In many settings, particularly outside of major research institutions, the absence of such specialized infrastructure delays the validation and clinical deployment of novel diagnostic tools.

There are also marked disparities in access to diagnostic technologies across care settings and regions. Infrastructural limitations in non-university hospitals and private providers often result in restricted access to essential molecular diagnostic assays, including RNA sequencing and molecular imaging. These disparities contribute to inconsistent testing practices, partial utilization of diagnostic data, and challenges in aligning diagnostic capabilities with the evolving requirements of precision therapies.

Clinical infrastructure and workflows

Moreover, clinical infrastructure within hospitals frequently remains unfit for purpose. Many facilities lack physical space and coordinated workflows necessary to deliver complex, personalized interventions.

Quotes:

"The fragmented nature of healthcare services, both in terms of physical infrastructure and digital systems, makes it difficult to implement coordinated care pathways for precision medicine."-Greece

"Many hospitals providing care are overwhelmed by the new personalised therapies. This indicates that the existing infrastructure is not sufficiently prepared for modern therapeutic approaches."-Germany



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“Many hospitals and clinics lack the necessary genomic testing facilities, AI-integrated diagnostics, and standardized data-sharing platforms.”-Bulgaria

*“ATMPs such as gene and cell therapies are clinically available but not widely implemented because hospitals lack infrastructure to administer them.”
-The Netherlands*

*“Fragmented and outdated hospital IT systems prevent seamless data exchange... Patient data is stored in multiple, disconnected hospital systems, making it difficult for clinicians to access real-time health records for personalized treatment.”
-The Netherlands*

“Hospitals are slow to invest in precision medicine infrastructure... Hospital administrators are unaware of available funding opportunities for integrating AI and molecular diagnostics.”-The Netherlands

*“Medical data is fragmented across different systems... There are no optimal solutions for communication and data exchange between medical services and laboratories... This significantly limits the use of medical data in precision medicine.”
-Romania*

“Access to molecular diagnostics, especially in private practices and non-university hospitals, is limited. Many diagnostic methods, such as RNA sequencing, are not always used... This leads to incomplete diagnoses and delays in identifying suitable therapeutic approaches.”-Germany

Good Practice	Country	Description
National strategy, Dutch Research Agenda – Personalised Medicine Route ³⁰	The Netherlands	The route has drawn up a Personalised Medicine Knowledge Agenda, as well as formulating seventeen themes that are crucial for its implementation.
Genomic Medicine Sweden (GMS) ³¹	Sweden	Through national collaboration, Genomic Medicine Sweden (GMS) supports healthcare in offering faster and more precise disease diagnostics. Its ambition is for larger regions to assist smaller ones by performing molecular analyses and sharing data, ensuring all patients can access precision diagnostics.
DIGENIA (Precision Medicine Unit in Molecular Oncology – Crete Node)	Crete, Greece	DIGENIA, part of the EDIMO network, is a precision medicine unit based in Crete that brings cutting-edge molecular diagnostics and clinical integration into the regional health system. It serves as a model of how infrastructure, clinical pathways, and digital data collection can converge within local healthcare services.

³⁰<https://www.nwo.nl/en/researchprogrammes/dutch-research-agenda-nwa/innovation-and-networks/routes/personalised-medicine-the-individual-at-the-centre/overview-of-the-route>

³¹ <https://genomicmedicine.se/en/>

Good Practice	Country	Description
ATMP- and Precision Medicine Centers at Swedish University Hospitals	Sweden	ATMP centres serve as a common entry point for companies looking to introduce their products into the Swedish healthcare system. Precision Medicine Centers provide infrastructure within the healthcare system where precision medicine is established and promote collaboration between healthcare and academia to support the development and implementation of precision medicine.
OMIQS-HES	Catalonia, Spain	OMIQ-HES project, an innovative technological platform that allows the integration of clinical, genomic and healthcare data to facilitate the management and analysis of genetic data in a centralized way. This initiative, represents a step towards more preventive, effective and safe healthcare, while optimising healthcare spending to ensure the sustainability of the system.
BeginNGS Greece (First Steps Newborn Genome Screening Program) 32	Greece	BeginNGS Greece is a pilot program aiming to implement rapid whole-genome sequencing to screen newborns for approximately 400 treatable genetic diseases, intending to facilitate early diagnosis and intervention for these conditions.

14. Regional inequities and centralization of services

The PRECISEU regional reports highlight that access to precision medicine remains uneven, with significant gaps between academic centers and other parts of the healthcare system. Centralised expertise, fragmented referral pathways, and unequal resource distribution continue to limit broader implementation.

Precision Medicine Access Gaps in Rural and Non-Academic Settings

A recurring issue across the regions is the concentration of infrastructure, expertise, and services within university hospitals and major urban centers. These institutions often serve as the main drivers of innovation, yet their central role creates structural barriers for smaller hospitals, rural providers, and non-academic institutions. As reported, these settings frequently lack the diagnostic capabilities, trained personnel, and financial resources needed to adopt precision medicine approaches.

Lack of Coordination Limits Patient Access to Precision Medicine

In several regions, patient registration and referral into precision medicine pathways is largely dependent on academic networks or motivated individuals. Without standardised outreach or coordinated screening efforts, many patients—particularly those outside university settings—are not identified or referred for personalised interventions.

High Costs and Complexity Exclude Smaller Providers from Precision Medicine

The reports also underscore that the complexity and high cost of implementing advanced diagnostics and therapies limit the participation of smaller institutions in national or regional

³² <https://www.firststeps-ngs.gr/>

initiatives. This reinforces disparities in access to personalised medicine beyond academic hubs.

Quotes:

Complex bureaucratic hurdles... such as the restriction of personalized medicine to university hospitals... limit access for patients in other facilities. This leads to an unequal distribution of resources... especially in rural areas.”-Germany

“Some hospitals offer comprehensive genetic screening, while others lack the necessary infrastructure, creating regional disparities in patient care.”-The Netherlands

*“Precision diagnostics are more common at university hospitals, as smaller regions struggle to establish such testing... due to cost and complexity.”
- Sweden*

INNOVATION ECOSYSTEM CAPACITY

15. Barriers to scalability in ATMP innovation and manufacturing

The innovation ecosystem supporting Advanced Therapy Medicinal Products (ATMPs) across the EU remains underdeveloped, with persistent structural and operational barriers that hinder scalability, patient access, and the translation of research into clinical practice. These challenges are especially pronounced for small and medium-sized enterprises (SMEs), academic institutions, and regions with limited infrastructure or fragmented support systems.

Structural barriers in manufacturing and supply systems

ATMPs require highly complex, resource-intensive, and strictly regulated production processes. This complexity, particularly for personalized, autologous therapies—demands specialized expertise and infrastructure, driving up costs and creating logistical hurdles. Manual handling remains the norm, with low levels of automation contributing to inefficiencies, heightened error risks, and constrained scalability.

Infrastructure gaps further complicate the landscape. Many regions, especially those outside established innovation hubs, lack access to GMP-certified manufacturing facilities and robust cold-chain logistics, which are critical for time-sensitive and patient-specific therapies. This uneven distribution of infrastructure exacerbates regional disparities in ATMP availability and limits broader EU-wide access.



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Limited access for SMEs and academic innovators

A fundamental barrier to innovation lies in the limited access to advanced biomanufacturing infrastructure for SMEs and research institutions. The current ecosystem favors large industrial players with in-house GMP capabilities and the capital to absorb high development and scale-up costs. In contrast, smaller actors often lack viable pathways to clinical-grade production, delaying or derailing the translation of early-stage research.

This infrastructure imbalance not only restricts innovation diversity but also diminishes the speed at which novel therapies and diagnostics can reach patients. The lack of shared or subsidized facilities means that even promising projects face high entry costs and logistical hurdles during the transition from proof-of-concept to clinical application.

Fragmentation and lack of coordinated support

Throughout the EU, the ATMP manufacturing ecosystem is characterized by fragmentation—between research, clinical, and manufacturing stakeholders. This disconnect leads to inefficiencies, misaligned incentives, and duplicative efforts. Few coordinated translational hubs or integrated value chains exist to guide early innovators through complex regulatory and manufacturing requirements. Moreover, the development of decentralized or flexible manufacturing models—such as modular GMP units or hospital-based facilities—remains nascent and under-supported.

Quotes:

“ATMP logistics and supply chains are complex due to stringent quality standards for these therapies. Manufacturing complexity of ATMPs, including strict GMP standards and scalability challenges for personalized therapies.”-Belgium

“The manufacturing and distribution of precision medicine treatments, especially ATMPs, present unique logistical challenges due to the complexity of their production and the stringent requirements for storage, handling, and transport.”- Italy

“The current regulation in Spain... does not allow the research centers to act as production sites for ATMPs for private sponsors, even if the centers are duly accredited for GMP. This limits the production capacity while potentially increasing the costs.”-Spain

Good Practice	Country	Description
ATMP-PIT ³³	Belgium	ATMP-PIT is a large collaborative umbrella project funded by the Walloon (BE) government and coordinated by the regional life sciences cluster (BioWin). It is a great example of pooling resources and centralized coordination.

³³<https://www.biowin.org/resources/the-atmp-pit-portfolio-an-atmp-collaborative-project-initiated-in-wallonia/>

Good Practice	Country	Description
Utrecht Cell Therapy Facility (CTF) ³⁴	The Netherlands	National hub for ATMP development and Cellular Therapy Cell- and tissue-based therapies and gene therapies hold great promise in the field of both immunotherapy and regenerative medicine.
NecstGen ³⁵	The Netherlands	A 4,000 m ² Good Manufacturing Practice (GMP) facility dedicated to the manufacturing and process development of cell and gene therapies.
NorthX Biologics ³⁶	Sweden	NorthX Biologics is a Swedish CDMO specializing in the development and GMP manufacturing of advanced biologics and ATMPs (Advanced Therapy Medicinal Products). Support service for both clinical trials and commercial supply
CCRM Nordic ³⁷	Sweden	CCRM Nordic in Gothenburg supports the commercialisation of advanced therapies in the Nordics and Europe, following the model of the Centre for Commercialization of Regenerative Medicine (CCRM) in Toronto, Canada. The initiative originated from the Swedish government and involves collaboration between academic institutions, industry, investors, and healthcare providers.
Strimvelis- Strategic multistakeholder partnership for ultra-rare disease therapies ³⁸	Italy	A partnership between Fondazione Telethon, San Raffaele Hospital, and GSK (Milan) led to the development, clinical testing, registration and access to market in Italy of Strimvelis, an ex-vivo gene therapy for ADA-SCID.
PRECISEU mapping of ATMP capacities in Europe ³⁹	EU	EATRIS, the European infrastructure for translational medicine, as part of the EU-funded PRECISEU project is leading the effort to map Advanced Therapy Medicinal Product (ATMP) capacities across Europe. This strategic initiative is designed to strengthen Europe's preparedness and infrastructure for delivering cutting-edge therapies, ensuring that patients across all regions have equitable access to life-saving innovations in ATMPs.
ATMP Guidebook for Innovators ⁴⁰	The Netherlands	The resource provides guidance on navigating the complex European and Dutch regulatory landscapes, offering tools to streamline the journey from preclinical development to market access.

16. Innovation ecosystem and coordination challenges across all fields of personalised medicine

The PRECISEU regional reports highlight that fragmented innovation ecosystems and limited coordination mechanisms are significant barriers to the development and implementation of personalised medicine across Europe. Although many regions demonstrate strong research capacities and a dynamic mix of stakeholders—including hospitals, SMEs,

³⁴ <https://www.onderzoeksfaciliteiten.nl/node/3928>

³⁵ <https://necstgen.com/about-us/>

³⁶ <https://www.nxbio.com/>

³⁷ <https://ccrmnordic.se/>

³⁸ <https://www.ema.europa.eu/en/medicines/human/EPAR/strimvelis>

³⁹ [MAPPING ATMP CAPACITIES ACROSS EUROPE - Preciseu](#)

⁴⁰ https://www.vereniginginnovatievegeneesmiddelen.nl/wp-content/uploads/2024/11/FAST_Guidebook-ATMP.pdf

universities, and research centres—these actors often operate in silos, with limited strategic alignment or cross-sector integration.

Uneven Collaboration Limits Innovation Spread

Collaboration between healthcare, academia, and industry remains inconsistent, particularly in translating research into clinical application. Innovation is frequently concentrated in university hospitals or select institutions, leaving smaller hospitals, regional providers, and rural areas with limited access to new developments. This centralisation creates gaps in capacity, infrastructure, and knowledge-sharing across the broader healthcare system.

Missing National Strategies and Innovation Support Structures

The lack of coordinated national or regional strategies often leads to duplicated efforts, fragmented pilot projects, and inefficient use of resources. Innovation support services—such as streamlined regulatory guidance, targeted funding mechanisms, and capacity-building programs—are underdeveloped in many regions. SMEs in particular face critical gaps in business development expertise, regulatory navigation, and engagement with health systems, hindering their ability to scale and contribute to implementation.

Without shared governance structures, long-term strategies, and integrated innovation pathways, the broader uptake of personalised medicine remains constrained.

Quotes:

“Weak integration between research and industry: collaboration between research institutions and industry is present but insufficient, leading to a gap between basic research and clinical application... Poor coordination among production sites and limited synergy between stakeholders further hinder progress.”-Italy

“Lack of strategic planning and coordination: no structured, long-term plan for the development of advanced therapies at the regional and national level. The absence of a national steering body and regional frameworks results in poor coordination between the different stakeholders.”-Italy

“Local and regional coordination efforts for ATMPs exist but lack federal-level coordination leading to inefficient use of resources and efforts.”-Belgium

“Policymakers... lack the instruments to enforce standardized practices and ensure consistency across regional and institutional actors.”-Greece

“Lithuania lacks a common personalised medicine (PM) strategy... Currently, there is no clear direction and coordination between various stakeholders... Healthcare providers: lack of coordinated approach to PM implementation and development...”-Lithuania

Good Practice	Country	Description
DARE-NL ⁴¹	The Netherlands	The Dutch infrastructure for cancer-specific ATMP Research (DARE-NL) is a unique partnership between all academic developers of Advanced Therapy Medicinal Products (ATMPs) in the Netherlands. The overarching goal of DARE-NL is to accelerate clinical testing of novel ATMPs for cancer patients to ensure timely and sustainable access to potentially curative treatment
Federated Health Innovation Network (FHIN) ⁴²	Belgium	Federated Health Innovation Network (FHIN) is a network of nine healthcare institutions in Belgium which are committed to collaborating in data sharing and optimization of care.
Dutch Innovative Medicines Association ⁴³	The Netherlands	The Association for Innovative Medicines builds bridges between pharmaceutical innovators, government and scientists to jointly tackle today's healthcare challenges. Through collaboration and innovation, we strive for direct solutions that benefit patients, healthcare and society in the Netherlands.
FAST ⁴⁴	The Netherlands	FAST (Centre for Future Affordable & Sustainable Therapy Development) is an independent national centre of expertise and collaboration, devoted to driving innovation in therapy development.
The law on personalized medicine using a quadruple helix model	Romania	Law 138/2023 is the first law in the world to formally recognize the right of citizens and patients to personalized medicine. The law was initiated as a follow-up to the personalized medicine policy adopted by the EU Council in 2015 and is the result of a multi-sectoral collaboration led by the Center for Innovation in Medicine in Romania. It was developed using the quadruple helix model—involving academia, the public sector, the private sector, and civil society—which later evolved into a penta helix model, incorporating a fifth stakeholder group for broader impact.

17. Access and integration of clinical trials and testbeds

Rapid advancement of personalised medicine depends fundamentally on the access to clinical trials and testbeds to validate new therapies, diagnostics, and technologies. However, insights gathered consistently point to persistent structural and operational barriers that hinder the scalability and effectiveness of these validation processes. These challenges slow the pace of innovation and compromise equitable access to advanced treatments.

Uneven Trial Infrastructure Limits Access

A main barrier is the uneven distribution of clinical trial infrastructure. Many healthcare systems lack the specialized personnel, dedicated trial units, and logistical support required to conduct precision medicine studies. Consequently, trial activity is concentrated in well-

⁴¹ <https://www.dare-nl.nl/>

⁴² <https://www.fhin.be/>

⁴³ <https://www.vereniginginnovatievegeneesmiddelen.nl/>

⁴⁴ <https://www.fast.nl/en/home/>

resourced urban academic centers, while smaller hospitals and facilities in rural or underserved areas are often excluded. This imbalance limits access to innovative treatments for large segments of the population.

Limited Clinical Access for SMEs

Small and medium-sized enterprises (SMEs) face additional challenges in accessing clinical settings for product testing and validation. The lack of dedicated testbeds and formal collaboration pathways with healthcare institutions restricts the generation of real-world evidence, which is vital for regulatory approval and clinical uptake.

Disconnect Between Trials and Routine Care

Moreover, clinical trials are frequently disconnected from routine care delivery. This separation leads to limited clinician engagement, poor alignment with standard care workflows, and reduced institutional support for trial activities. As a result, the integration of trial outcomes into everyday clinical practice is often delayed or overlooked.

Fragmented Data and Coordination Gaps Limit Trial Recruitment and Scale

Patient recruitment further complicates trial execution, particularly for studies involving rare diseases or requiring specific genomic criteria. Fragmented health data systems and the absence of integrated patient registries impede the timely identification and enrollment of eligible participants. These difficulties are compounded by a lack of centralized coordination mechanisms at national or regional levels, resulting in inefficiencies and missed opportunities for collaboration. Without harmonized frameworks and standards, the development of multicenter and cross-border trials remains limited, ultimately constraining the broader implementation of personalised medicine.

Quotes:

*"Hospital infrastructures capable of conducting early-stage ATMP trials are scarce, particularly outside of oncology, further limiting the availability of trials."***-Italy**

"Slow patient recruitment and failure to deliver promised patient numbers in previous trials make Sweden less attractive for conducting new studies."
-Sweden

*"Limited funding for precision medicine trials makes it difficult to generate evidence needed for regulatory approval."***-The Netherlands**

"Culture is a key issue, as there are vastly different behaviors across clinics, despite similar conditions in terms of budget and workload. ... It is possible to work in alternative ways to organise clinical trials, but there is resistance.. One limiting factor is outdated workflows that are difficult to change..."
-Sweden

*"Hospitals struggle to participate in clinical trials due to bureaucratic inefficiencies, regulatory hurdles, and lack of resources."***-The Netherlands**

*"Clinical trials for precision medicine treatments are expensive, and many hospitals and research centres struggle to secure funding."***-The Netherlands**

Good Practice	Country	Description
NJ-ACTS ⁴⁵	USA	New Jersey Alliance for Clinical and Translational Science (NJ ACTS) – Three major universities in New Jersey have partnered to collectively issue research grants, offer trainings and mentorship, support informatics, collaborations with community groups and industry, programs that address underserved populations, and improved access to clinical trials.
Swetrial ⁴⁶	Sweden	SweTrial is a newly proposed national partnership in Sweden that unites industry, academia, healthcare, patients, and regulators to strengthen the country's capacity for clinical drug trials. Led by the Swedish Medical Products Agency
European Reference Network (ERN) for Rare Diseases ⁴⁷	EU	The European Reference Networks (ERN) facilitate the knowledge-sharing among researchers and clinicians across Europe. They support rare disease diagnosis, treatment, optimisation and patient identification for clinical trials.

CONCLUSION AND WAY FORWARD

This report, developed within the framework of the PRECISEU project, highlights the complex and interrelated barriers that hinder the development, market entry, and implementation of personalised medicine across Europe. Drawing on regional insights from ten European regions, the findings point to persistent challenges in areas such as health data access, financing, regulation, competence and awareness, healthcare system readiness, and innovation ecosystems. While these barriers vary in form and intensity across contexts, they collectively impede the ability of health systems, innovators, and especially SMEs to fully contribute to the development and implementation of personalised medicine.

At the same time, the report identifies several promising practices that demonstrate how targeted investment, cross-sector collaboration, and SME-oriented initiatives—such as shared manufacturing infrastructure—can begin to overcome these obstacles. This mapping of barriers and emerging solutions provides a critical foundation for understanding where and how support should be directed to strengthen the innovation process and foster the successful development and adoption of personalised care.

Looking ahead, PRECISEU will build on this foundation by developing a joint roadmap and model to support a future open innovation collaboration infrastructure for personalised

⁴⁵ <https://njacts.rbhs.rutgers.edu/>

⁴⁶ <https://www.lakemedelsverket.se/sv/nyheter/swetrial-vassar-sveriges-konkurrenskraft-inom-kliniska-provningar>

⁴⁷ https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/european-reference-networks_en



medicine in Europe. This next phase will involve the active engagement of experts and stakeholders across all participating regions to co-create concrete, evidence-based actions at the regional, national, and EU levels. The roadmap will define good practices and scalable approaches for harmonising testbed collaborations, supporting sustainable business models, strengthening financial and procurement strategies, and addressing regulatory and market access needs.

By aligning efforts across regions and stakeholder groups, this work aims to enable more coherent policy responses, targeted innovation support, and scalable implementation strategies. Ultimately, the coordinated actions initiated through PRECISEU will help ensure that personalised medicine innovations can reach patients faster, more equitably, and with greater impact across Europe.



APPENDIX A: COUNTRY FACT SHEETS

The following section presents dedicated regional/country fact sheets that provide an overview of the current state of personalised medicine in each participating area. These fact sheets highlight region-specific strengths and challenges, offering insight into local contexts, capacities, and needs. By presenting this information in a structured, comparative format, the fact sheets contribute to a more granular understanding of how personalised medicine is evolving across Europe. This region-specific perspective supports more targeted policymaking and helps identify opportunities for collaboration, adaptation of best practices, and coordinated action at both local and European levels.



Region of Flanders, Belgium



Overview: Flanders, Belgium is a prominent life sciences region in Europe with coordinated efforts to boost ATMPs, digital health, and precision oncology. Strong partnerships among universities, research hospitals, patient organizations, and biotech companies foster a fertile ground for innovation. The region is highly active in EU-level collaborations and hosts several major networks focused on data sharing, logistics, and regulation, such as the Federated Health Innovation Network (FHIN) and at.las. Cluster organizations like Biovia and BioWin play a central role in connecting regional and cross-border initiatives. While government-backed initiatives have made strides in digitizing health data, challenges persist around interoperability, data reuse, and the standardization of regulatory pathways—particularly under GDPR and hospital exemption rules. Multilevel governance, misaligned reimbursement incentives, and fragmented IT infrastructure continue to limit the scalability and harmonization of precision care across Belgium.



Challenges

Data Governance & Infrastructure; Fragmented, non-standardized, and siloed health data stored in non-searchable formats.

Regulatory & Legal Complexity; complex regulations, due to a combination of medical, regulatory and financial factors; additional complexity for Hospital exemption. GDPR challenges; inconsistent EU-level interpretations.

Financial & Reimbursement Constraints; High cost of ATMPs; complex and evolving reimbursement models for ATMPs; underfunded digital infrastructure.

Health System Integration; Poor coordination between institutions; unequal access to expertise and testing facilities.

Skills & Awareness; Growing need for structured national ATMP trainings; low public and provider awareness of personalized options.

Political & Institutional Fragmentation; Complex multi-level governance; inconsistent strategies across regions. **Collaboration & Ecosystem Coordination;** Regional clusters exist but lack national integration; duplicated efforts in project funding.

Infrastructure & Logistics; Complex and costly ATMP supply chains; strong and growing network of GMP facilities for ATMPs but need for scalable GMP compliant production systems. Lack of coordinated strategies between governments, academic institutions and industry.



Bulgaria



Overview: Bulgaria is developing a growing ecosystem for precision medicine and digital health, supported by EU funding and a network of AI startups, research institutions, and healthcare innovators. Key national initiatives, such as the VELES Project, aim to create a smart health data space aligned with the EHDS, emphasizing federated learning and secure secondary data use. Despite promising momentum, systemic barriers—including complex regulatory frameworks, underdeveloped healthcare IT infrastructure, low public and clinical awareness, and fragmented data systems—continue to limit the widespread adoption of personalized medicine. The country also faces challenges in implementing AI-driven healthcare solutions due to skepticism among clinicians and strict data governance laws. Strategic investments, regulatory reform, and stakeholder education will be essential for translating Bulgaria’s innovation potential into tangible healthcare outcomes.



CHALLENGES

Regulatory Barriers; Lengthy and complex approval processes slow down the adoption of precision medicine solutions, particularly AI-driven healthcare innovations.

Financial Barriers; High costs and lack of structured reimbursement pathways limit patient access and discourage innovation in personalized medicine.

Healthcare System Barriers; Many hospitals lack the infrastructure and expertise needed for genomic testing and AI-driven diagnostics.

Data Access & Integration Challenges; Siloed hospital systems and strict GDPR compliance restrict secondary use of health data for research and innovation.

Lack of Public Awareness & Clinical Trust; Low awareness among patients and skepticism among clinicians reduce adoption of AI-supported diagnostics and genomic testing.



Catalonia, Spain



Overview: Catalonia is recognized as a dynamic innovation hub in Spain, with strong institutional support, advanced digital infrastructure, and pioneering programs like the Catalan Plan for Precision Oncology. The region benefits from a large and diverse innovation ecosystem including leading hospitals, research institutions, startups, and public health authorities. Key strengths include experience in risk-sharing agreements, CAR-T therapy development under hospital exemption, and data access programs like PADRIS. However, systemic barriers remain. These include complex and rigid regulatory processes, fragmented data infrastructure, lack of long-term strategy alignment, financial constraints, and insufficient awareness and training in personalized medicine. To sustain its leadership, Catalonia should consider fostering greater alignment across initiatives, develop clear decision-making pathways, promote interoperability, expand innovative financing, and enhance multi-stakeholder education on PM.



CHALLENGES

Regulatory Complexity; PM innovations face unclear, lengthy, and inconsistent regulatory processes, including barriers to data access and ATMP production by research centers.

Fragmented Operational Systems; Lack of integration and structured decision-making in hospitals hinders PM adoption and innovation testing.

Financial Constraints; High costs of therapies and diagnostics, lack of flexible reimbursement, and absence of public innovation procurement models, delay access and scale-up.

Competency and Awareness Gaps; Healthcare professionals, patients, and policymakers lack adequate understanding and training in PM, bioinformatics, and value-based procurement.

Limited Data Interoperability; Fragmented IT systems and inconsistent data standards impede access to high-quality, reusable health data across institutions.

Crete, Greece



Overview: The Region of Crete is emerging as a promising innovation node in the Greek precision and personalized medicine landscape, supported by strong academic institutions, a growing number of SMEs, and pioneering efforts in genomic research. Crete benefits from national initiatives such as the Hellenic Network of Precision Medicine, and the region's participation in AI and genomic pilot programs. The region has also formally adopted 'Health and Well-being' as a strategic priority in its Regional Smart Specialisation Strategy (RIS3), and has been established as a four stars Reference Site ecosystem for Active and Healthy Living. It is home of the European Digital Innovation Hub for Smart Health: Precision Medicine and Innovative e-Health Services. These activities highlight the Region's commitment to support cross-sectoral innovation in digital health, personalized medicine, and life sciences. This strategic positioning further amplifies the visibility and impact of ongoing initiatives, enabling Crete to attract research funding and develop competitive capabilities in precision care, chronic disease prevention, and healthy ageing. Despite having the only integrated regional healthcare information system in Greece, Crete still contends with many national-level systemic issues. To fully realize its potential, Crete should improve infrastructure, streamline data readiness and governance, and foster stronger collaboration across public and private stakeholders. Aligning with the European Health Data Space framework, will be crucial not only to unlock the full value of existing health data assets but also to ensure interoperability, trust, and scalability. These efforts will further strengthen Crete's position as a leading innovation hub in precision medicine and digital health, capable of delivering tangible benefits to citizens through more effective, personalized, and preventive care services.



CHALLENGES

Limited Access to High-Quality Data; Data fragmentation and lack of interoperability limit personalized care and large-scale research opportunities.



Cost and Reimbursement Issues; Genomic tests and therapies are underfunded or not reimbursed, limiting equitable access.

Digital Health Literacy; Healthcare providers and patients lack training to effectively use genomic data and digital tools.

Lack of AI Algorithm Validation Frameworks; No national standards exist for validating AI tools in clinical settings.

Regulatory Challenges; Outdated or unclear regulations delay approvals and implementation of PM technologies.

Data Privacy and Security Concerns; Uncertainty around data usage deters participation and risks legal non-compliance.

Healthcare Infrastructure; Rural and regional healthcare centers lack capacity to implement and scale PM solutions.

Ethical and Societal Concerns; Fear of genetic discrimination and inequitable access reduce patient trust and engagement.

Lack of National Data Governance; No clear structures or roles for data sharing and secondary use.

Selective Availability of Real-World Data; RWD are not systematically collected or accessible.

Legal Ambiguity on Secondary Use; Ambiguities in GDPR interpretation, ethical approvals, and responsibilities across authorities hinder data reuse.

Data Harmonization Issues and Fragmented Systems ; Lack of nationally enforced standards like HL7 FHIR and OMOP-CDM hinders integration.

Limited Interoperability and Orphan IT Systems; Legacy IT systems lack upgrade paths or APIs for data sharing.

Misaligned Incentives; Data custodians lack motivation to share data with researchers and innovators.

Emilia-Romagna, Italy



Overview: Emilia-Romagna stands out as one of Italy's most advanced regions for healthcare innovation, combining a high-performing regional health service with a thriving ecosystem of universities, technopoles, IRCCS research hospitals, public-private partnerships, and cutting-edge infrastructure. The region integrates precision medicine into its Smart Specialisation Strategy, supported by advanced diagnostics, biobanks, digital health initiatives, and AI-powered computational capacity (e.g., the Leonardo supercomputer). Anchored by five IRCCS centres and supported by innovation networks like the High Technology Network, Clust-ER Health and ART-ER, Emilia-Romagna leads in applying genomics, AI, and ATMPs in clinical care. Participation in major EU initiatives (e.g., PRECISEU, Vanguard Initiative Smart Health Pilot) and national investments like HEAL Italia as well as the regional oncology and haemato-oncology network further emphasise its commitment to personalised healthcare. However, challenges remain in strategic alignment, funding, regulatory clarity, and workforce development, which impact the scalability and sustainability of precision medicine implementation across the region.



CHALLENGES

Lack of Strategic Planning and Coordination; Fragmented efforts and poor alignment between stakeholders hinder health data use and innovation scalability.

Weak Integration Between Research and Industry; Insufficient synergy between academic research and industrial application slows translation into clinical practice.

Regulatory and Reimbursement Challenges; Lack of Diagnosis-Related Groups for ATMPs and slow policy implementation delay access and financial sustainability.

Fragmented Training and Skill Shortage; Gaps in multidisciplinary training and an aging healthcare workforce constrain innovation and capacity.

Limited Funding and Investment; Low venture capital availability and late-stage funding hinder commercialization of precision medicine technologies.



Limited R&D Companies in Precision Medicine; Few private companies are involved in innovation, especially in gene and cell therapy, which remain mostly public-sector driven.

Regional and National Disparities; Uneven infrastructure across Italy limits consistent access to precision healthcare services.



Baden-Württemberg, Germany



Overview: Baden-Württemberg is a national frontrunner in Germany for precision medicine, powered by a network of elite university hospitals, research institutions like the DKFZ, and innovation centers such as ZPM in Tübingen, Ulm, Heidelberg and Freiburg. With strong European and national collaborations, the region has pioneered models for genome sequencing, data-driven diagnostics, and personalized oncology. Pilot initiatives, such as pay-for-performance frameworks and patient-integrated care networks, demonstrate scalable potential. However, persistent challenges—such as fragmented data systems, uneven funding structures, regional disparities in diagnostics access, and restrictive certification limited to university hospitals—undermine equitable adoption. Lack of public and clinical education on personalized medicine, coupled with high costs, complex bureaucracy, and limited interoperability, remain significant barriers. Unlocking the full potential of this ecosystem requires streamlined reimbursement, broader certification criteria, nationwide IT harmonization, and strengthened patient engagement strategies.



CHALLENGES

Financing Barriers; A lack of health insurance coverage for scientific diagnostics and therapy in personalised medicine, selective contract coverage and insufficient support for rare diseases lead to inequalities and delayed access.

Bureaucratic and Regulatory Constraints; Complex approval structures and fragmented reimbursement hinder cross-regional and cross-border access to precision therapies.

Exclusivity of Certification to University Hospitals; Only university hospitals can be certified as precision medicine centers, excluding capable regional hospitals and clinics.

Lack of Integrated Data Infrastructure; Isolated IT systems and inconsistent documentation slow down innovation and real-time precision care implementation.



Limited Patient Awareness and Communication; Patients often lack transparent access to treatment information, requiring proactive efforts to obtain diagnostics and therapy options.

Shortage of Skilled Professionals; Insufficient training in molecular diagnostics and advanced therapies limits implementation outside leading university centers.

High Costs for Personalized Therapies; Small clinics and non-academic hospitals face cost barriers, limiting access to next-generation treatments.

Limited Drug Access & Off-label Approval; Inconsistent reimbursement for off-label therapies restricts availability for rare or non-standard treatment approaches.

Political and Institutional Barriers; Certification and funding are politically skewed, restricting innovation scalability beyond academic institutions.

Fragmented Use of Research and Secondary Health Data; Inconsistent data access, inconsistent governance and varying federal regulations, as well as high privacy regulations, hinder the effective reuse of data..

Lithuania



Overview: Lithuania's precision care ecosystem is emerging with strong scientific foundations, robust digital infrastructure, and centralized health data systems like ESPBI IS. The country benefits from EU support programs, research excellence, and growing public sector involvement. However, precision care adoption is hindered by the lack of a national strategy, complicated legal and administrative procedures, insufficient training for healthcare professionals, and limited private sector engagement. High costs, low investment readiness, and fragmented data access further constrain innovation and market scalability. Unlocking Lithuania's potential in personalized medicine will require clear national coordination, increased stakeholder collaboration, better funding structures, public awareness campaigns, and systematic improvements to data governance and workforce training.



CHALLENGES

Lack of a National Personalised Medicine Strategy; Absence of a cohesive national strategy leads to fragmentation, reduced investment, and slow implementation of PM initiatives.

Complicated Legal Framework and Administrative Burden; Unclear regulations and bureaucratic approval processes delay innovation and increase costs for precision care developers.

Competency Gaps; Healthcare professionals and decision-makers lack adequate training in PM technologies, limiting adoption and effectiveness.

High Costs and Investment Challenges; Substantial costs for R&D and limited investor interest hinder the growth and commercialization of PM solutions.

Low Public Awareness; Limited public understanding of PM reduces patient demand and impedes widespread implementation across the health system.



The Netherlands

Overview: The Netherlands boasts a highly developed precision care ecosystem, recognized for its robust research infrastructure, integrated healthcare system, and strong tradition of public-private collaboration. Anchored by its network of University Medical Centers (UMCs), cutting-edge biotech firms, and patient advocacy organizations, the country has positioned itself as a leader in ATMP development, AI-driven diagnostics, biomarker research, and health data governance. The national Health-RI initiative aims to build a federated, interoperable health data infrastructure that supports research, clinical trials, and personalized treatment decisions. The Netherlands' compact geography and collaborative culture foster its role as an ideal testbed for precision medicine. However, despite its strengths in early-stage innovation and pilot testing, full-scale clinical adoption is often hampered by regulatory, financial, and infrastructural constraints. Active stakeholder engagement, policy support, and continued investment are key to realizing the country's full potential in equitable, data-driven precision healthcare.



CHALLENGES

Legal and Regulatory Complexity; Fragmented EU regulations and inconsistent GDPR interpretations is very time consuming and delay market access and multinational trial implementation.

Healthcare System Integration; Hospitals face challenges in adopting precision care due to legacy systems, slow workflows, and lack of standardized protocols.

Financial Constraints; High costs and lack of clear reimbursement pathways hinder access to precision therapies and diagnostics.

Competence and Awareness Gaps; Clinicians, patients, and policymakers often lack training and understanding of precision medicine, genomics, and AI. However, the major overarching hurdle is the lack of awareness and support for managing the entire process—from discovery to implementation, including reimbursement.

Data and Infrastructure Barriers; Outdated and non-interoperable IT systems complicate data sharing and hinder AI tool integration.

Reimbursement Uncertainty; Opaque processes and outdated cost-benefit models make it difficult for innovative therapies to gain approval.

Limited Clinical Trial Participation; Hospitals struggle with bureaucracy, capacity, and incentives needed to engage in precision-focused clinical trials.

Fragmentation of the ecosystem; Decentralised approaches lead to inconsistencies in diagnostics, care delivery, and innovation adoption. In additions, innovation often exists in isolated pockets rather than as a cohesive system.

Slow AI Integration; Despite strong R&D, adoption of AI tools in clinical workflows is slow due to validation and infrastructure challenges.

Secondary Use of Health Data; Legal, ethical, and technical barriers restrict the reuse of anonymized patient data for research and innovation.

Bias Toward Drug-Centric Innovation; Personalized medicine encompasses much more than just drugs; it also involves technology and diagnostics development. Non-pharma innovations like diagnostics and prevention receive less defined workflows, investment and policy attention.

Industry vs patients drivers: Currently, drug development in personalized medicine is largely industry-driven, with companies defining the key questions for their drugs. – However, ideally, research questions would originate from patient needs, with trials designed in collaboration with both patients and industry stakeholders.

North East Region of Romania



Overview: The North East region of Romania demonstrates growing ambition in the field of precision medicine, supported by initiatives like the ROGEN project, MEDIC-NEST Metalcluster in precision medicine, PRECISEU participation, and the development of the TRANSCEND research infrastructure. Despite promising local momentum and high engagement among medical institutions, the region faces deep systemic challenges—ranging from fragmented data systems and underfunded infrastructure to skills shortages and lack of standardized genomic services. While Romania has adopted progressive legislation such as the Law on the Right to Personalized Medicine, implementation lags behind due to unclear strategies, minimal funding, poor inter-institutional coordination, and the absence of integrated national data platforms. Unlocking the potential of precision care in this region requires robust investment, coordinated policy reform, strategic development of bioinformatics capacity, and alignment with EU digital health standards and interoperability goals.



CHALLENGES

Lack of Integrated Digital Infrastructure; Fragmented and non-interoperable health data systems hinder the patient journey and personalized care planning.

Insufficient Access to Genomic Testing & Indigenous Data; Few public services offer genetic testing, and current analyses do not reflect the Romanian population's specific genetic context.

Limited Investment in Infrastructure; Public hospitals lack the funds for advanced equipment and reagents, with most budgets consumed by operational costs.

Regulatory Gaps in Genomic Data Use; Lack of legal frameworks on data governance, sharing, and genomic services delay strategic development.

Financial Constraints on Precision Therapies; Low reimbursement rates and lack of diversified funding models limit access to advanced diagnostics and treatment.



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Skills Shortage & Training Deficits; There are too few trained oncogeneticists, bioinformaticians, and PM-aware clinicians.

Low Public and Professional Awareness; Limited patient education and provider familiarity with PM reduces adoption and trust.

Lack of National and Regional Coordination; Projects often operate in silos due to poor interinstitutional communication and unclear role division.

Slow Technology Transfer; Long delays in bringing nanomedicine and other innovations from lab to clinic due to inefficient pathways.

Inadequate Data Access Frameworks; No unified mechanism or infrastructure exists for accessing or reusing clinical/genomic data for research.

Västra Götaland, Sweden



Overview: Sweden aspires to be a global leader in life sciences, with a strong focus on personalised medicine. National “bottom-up” personalised medicine initiatives centered around integrating genomics into healthcare (e.g., via Genomic Medicine Sweden - GMS), and infrastructure projects like the National Genomics Platform (NGP) are advancing clinical and research use of genomic. Other initiatives, such as the establishment of regional ATMP and Precision Medicine centers at university hospitals and their coordination activities, are supporting harmonization of national efforts.

Western Sweden is well positioned for precision medicine, with several initiatives and well-developed cluster collaborations. Major players such as Sahlgrenska University Hospital, Sahlgrenska Academy, and AstraZeneca are present, alongside entrepreneurial innovation hubs such as Sahlgrenska Science Park and the life science district GoCo Health Innovation City. In addition, the non-profit initiative, CCRM-Nordic, which supports the scaling and manufacturing of ATMP has recently been established.

Despite strong research and a well-developed ecosystem, successful SME growth stories in personalised medicine in West Sweden are limited. Funding challenges persist due to limited commercialization focus, few specialist investors, and premature IPOs. Prioritizing fewer, well-funded, high-quality startups can reduce fragmentation and enhance outcomes in personalised medicine.



CHALLENGES

Commercialization Responsibility Gap; Sweden’s professor’s privilege gives researchers ownership of their inventions but places the burden of commercialization on them. Without adequate institutional support, this may hinder precision medicine innovation.



Insufficient Innovation Funding; Limited long-term capital and a shortage of specialist investors hinder the development and scaling of precision medicine startups.

Limited Access to Testbeds; A shortage of physical and virtual environments for companies to validate and refine innovations with healthcare stakeholders.

Challenging Clinical Trial Conditions; Healthcare culture, resource constraints, and high costs limit Sweden's competitiveness in attracting and conducting clinical trials.

Complex Reimbursement Processes; The reimbursement process is complex, involving both the NT Council and TLV, which can delay patient access and hinder market uptake

Lack of Payment Models; No established risk-sharing or outcome-based payment schemes exist, weak data systems for tracking hospital-administered ATMPs, make outcome-based payment models difficult to implement.

Barriers to Health Data Sharing; Legal (GDPR, Patient Data Act) and technical fragmentation prevent efficient cross-regional data use for research and innovation.

APPENDIX B: REGIONAL REPORT TEMPLATE

Regional report
Region [XXX]

Content

Instructions for use (Please remove this text before distribution):

1. Summarize your interview results in this document.
2. Send out the summarized result to your workshop participants 2 weeks ahead of the workshop for them to prepare and reflect on finding.
3. At the workshop, participating stakeholders will discuss and provide their common view of: 1) Largest Barriers and 2) Strength and weaknesses.
4. Ask participants to comment if needed on: 3) Best practices and on 4) Accessibility to secondary health data.

Largest barriers for market and patient access to precision care innovations

Instructions for completing the template (Please remove this text before distribution):

1. **Description:** Provide a detailed explanation of the barrier, clearly outlining why it obstructs the adoption of business innovations in precision care.
2. **Affected parties:** Identify the organizations or target groups impacted by this barrier, and describe how they are affected.
3. **Impact assessment:** Evaluate the extent to which the barrier hinders the uptake of innovations in precision care.
4. **Recommended actions:** Specify actionable steps that can be taken to address the barrier, including which organizations, target groups, or roles should be involved in implementing these actions.

Barrier 1. [Name barrier with a short description]

Detailed description:

Text...

Affected parties:

Text..

Impact:

Text...

Recommended actions:



Barrier 2. [Name barrier with a short description]

...

Barrier X. [Name barrier with a short description]

...

COPY & PASTE TEMPLATE IF NEEDED OR DELETE EMPTY

2. Regional strengths and weaknesses in precision care

Instructions for completing the template *(Please remove this text before distribution):*

Assessment of strengths and weaknesses in precision care within the region. Please prefill 2-3 strengths and weaknesses. In workshop, participants will provide additional information.

Definitions:

- **Strengths:** Key positive characteristics or capabilities unique to the region that provide a competitive advantage in precision care.
- **Weaknesses:** Challenges or limitations within the region that hinder its potential or place it at a disadvantage compared to others.

Provide a thorough analysis of the region's major strengths and weaknesses in precision care, focusing on how these factors influence its overall position and opportunities in this field.

Text...	Text...
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3. Best practices for accessing innovations in precision care

Instructions for completing the template *(Please remove this text before distribution):*

Ask workshop participants to add/comment in the on best practices as this section will not be part of workshop discussions.

Detailed description of actions/activities implemented: Provide a comprehensive explanation of the best practice, highlighting why it is effective in promoting the adoption of business innovations in precision care.

Key players/organizations involved: Identify the organizations involved and detail their respective roles and contributions.

Impact assessment: Evaluate the extent to which the best practice influences the adoption of innovations in precision care.

Transferability: Outline the requirements and conditions necessary for implementing the best practice in other regions.

Best practice 1. [Name best practice with a short description]

Detailed description of actions/activities implemented:

Text...

Key players/organizations involved:

Text..

Impact assessment:

Text...

Transferability:

Text...

Best practice 2. [Name best practice with a short description]

...

Best practice X. [Name best practice with a short description]

...

COPY & PASTE TEMPLATE IF NEEDED OR DELETE EMPTY

4. Accessibility to secondary health data

Instructions for completing the template (Please remove this text before distribution): In this section we are highlighting the barriers for accessing health data . You do not need to provide answers to all headlines below if you have not captured the information in the interviews. Workshop discussions may provide additional information during discussions of the largest barriers.

Description how Health Data for secondary use is accessed (by companies or research institutions):

Text...

Barriers for accessing Health Data (regulatory or other barriers):

Text..

Opinions on how accessibility to secondary health data should be in the future:

Text...

If examples of good practices, what does it look like and why does it work well:
Text...

